

EPA Registration No.
88966-1
vol. 1

PYXIS REGULATORY CONSULTING, INC.

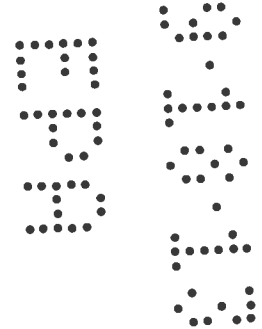
4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

September 16, 2013

OVERNIGHT DELIVERY

Richard Gebken (PM 10)
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202



RE: Tru Prodigy
VetGuard for Cats (EPA Reg. No. 88966-1)
Response to Data Deficiencies in Agency Letter Dated August 28, 2013
OPP Decision No. D-481141

Dear Mr. Gebken,

On behalf of Tru Prodigy, I am submitting a response to the data deficiencies identified in your letter dated August 28, 2013 for the amendment for the subject product.

1. On September 5, 2013, I provided Carmen Rodia with a detailed explanation from Tru Prodigy regarding the use of the "VETIQ" logo on the label. A copy of that two page explanation is enclosed for your consideration. Tru Prodigy agrees with your statement that the Agency has not reviewed or approved this logo or the statement "Free app at [www. VetGuardPlus.com](http://www.VetGuardPlus.com)". One of the primary objectives of this amendment was to add the "VETIQ" logo and reference to the app so that EPA could approve these statements on the label.

I understand that the "VETIQ" logo and the app statement were discussed during a meeting between EPA and Tru Prodigy on April 30, 2013. Mr. Rodia requested further information on the log and app by e-mail dated May 22, 2013, which was provided in a letter dated May 31, 2013 from Mr. James Rathvon and Ms. Cristen Rose. A copy of that letter is attached. As noted in their letter,

"“VETIQ™” is an umbrella brand name used for all products (both pesticidal and non-pesticidal) manufactured or formulated by or on behalf of either Tru Prodigy or its corporate affiliate, TruRx. The app enables customers to enter and track expenses and medications for their pets, and can be programmed by the user to provide reminders. Users also can use the app to enter and then print the vaccination history for their pets.”

Thus, the app provides a type of database into which a user can enter and track information about their pet or pets. I trust that the information provided in this letter will be sufficient for your consideration of the "VETIQ" logo and statement regarding the app on the product labels.

2. Regarding the optional marketing statement "Made in the USA", the reference to 40 CFR § 152.43 no longer applies. Part of this July 19, 2013 amendment involves an amended CSF (dated July 19, 2013) which is a Basic CSF in the format approved by EPA¹. That amended CSF includes the alternate CRP producer which is located in the US. Approval of that CSF is contingent on acceptability of the child resistant packaging data that were submitted with the amendment.

In any event, registrants are permitted to add optional marketing statements such as "Made in the USA" by non-notification² as long as the statement complies with other regulatory requirements. Statements concerning where a product is made, such as "Made in the USA", are under the regulatory jurisdiction of the Federal Trade Commission. Accordingly, for purpose of seeking EPA's approval of this amendment, Tru Prodigy will remove the statement "Made in the USA" from the proposed label.

The following documents are enclosed

1. Application for Pesticide Registration (EPA Form 8570-1)
2. One (1) copy of the revised label with changes tracked
3. Three (3) copies of the revised label with changes accepted
4. A CD containing an electronic version of the labels
5. Certification with Respect to Label Integrity
6. Letter of Authorization

Please contact me by email at Ann@PyxisRC.com or by phone ((253) 853-7369) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures

cc: M. Johnson
L. Rossi

¹ Memorandum from Jeff Herndon to the Office of Pesticide Programs Staff and Office of Chemical Safety and Pollution Prevention dated November 28, 2011. Confidential Statement of Formula for End-Use Products (EPs) and Manufacturing Use Products (MUPs).

² Pesticide Registration Notice 98-10, Section IV.F.5, Non-Pesticidal Characteristics, Where product is made. Oct 22, 1998.

VETIQ BRAND STRATEGY

VetIQ is a brand developed to provide an edge in an increasingly competitive pet product marketplace. It was developed to help customers understand what they can expect from our products, and it differentiates our offerings from our competitors'. VetIQ was also derived to help the consumer easily recognize we are a pet products brand.

The foundation of our brand is the logo. Because it's a potential benefit to the consumer, using the logo on packaging, websites, promotional materials, and other advertising is imperative to it's usefulness in the marketplace, and to the consumer.

Our company mission is to provide quality pet products at prices people can afford. We desire to provide the best information possible so that pet owner's can make informed decisions for their pets. For this reason we developed the VetIQ brand strategy including brand messaging, advertising, distribution, etc. In order for this strategy to be affective we need consistent, strategic messaging of our company's products in all forms of media.





Brand Architecture

True Science, LLC is a holding company that sells quality pet products under a number of brands, at prices consumers can afford. These include VetIQ™ and Betsy Farms™ – two brands currently available for sale at retailers nationwide; and Lil' Tex Ranch™ and Delightibles™ – two brands that are under development and will ship in 2014. True Science, LLC is similar to companies like Procter & Gamble and Reckitt Benckiser that don't merchandise products under the company name, but rather under separate brands, like as Gillette, Olay, Crest, Herbal Essences, Lysol, and others. More information with regards to True Science can be found on our corporate website, www.truescience.com. Tru Prodigy is a wholly owned subsidiary of True Science.

VetIQ™ is the flagship brand for True Science, LLC. VetIQ™ offers pet prescription medications, over-the-counter flea & tick preventatives, and other health and wellness supplements for America's pets, at savings to other branded alternatives.

VetIQ™ products include VetGuard Plus® Flea & Tick control, Minties® Dental Treats, VetIQ™ Hip & Joint, VetIQ™ Vitamin Chews, VetIQ™ Skin & Coat, VetIQ™ Pill Treats, TruProfen™ and Heart Shield™ Plus. Each product is designed to address a particular health benefit. Retailers that carry VetIQ™ products include Walmart, Sam's Club, Kroger, Kmart, Costco and Rite Aid. For more information, please visit www.VetIQ.com.

In Summer 2013, True Science launched a new brand of products, Betsy Farms™. Betsy Farms™ products are different from VetIQ products in that they are simple *dog treats* without a particular functional benefit. Market research and conventional wisdom indicate that consumers desire brands that simplify the buying decision, and that brands should address wants and needs that are unique and meaningful to them. Our Delightibles™ brand, planned for 2014 launch, will provide quality *cat treats*, made in the USA.

Each of the brands that True Science employs a token brand strategy. For example, VetIQ products VetGuard Plus, Minties, Hip & Joint, etc., have the VetIQ logo on the principle display panel of the package or in other consumer communications. May other brands do this including Kraft (Kraft Jello, Kraft Oreo, and Kraft Velveeta), Gillette (Gillette Fusion, Gillette Venus, and Gillette Mach3), Crest (Crest Pro Health, Crest White Strips, Crest Scope Mouthwash). This provides a common brand for products within the line and is meaningful to consumers. Consumers have learned to trust the VetIQ brand name. As they are happy with one product in the VetIQ™ line, they may have interest in others. Marketing VetIQ™ in this way provides a halo effect – promoting one product raises awareness and trial of others.

PALEY
ROTHMAN
GOLDSTEIN, ROSENBERG, LIG & COOPER
CHARTERED

4800 HAMPDEN LANE, 7th Floor
BETHESDA, MARYLAND 20814
MAIN TELEPHONE: (301) 656-7603
MAIN FAX: (301) 654-7354

May 31, 2013

James P. Rathvon
JRathvon@paleyrothman.com
Dir: (301) 951-9342
Fax: (301) 652-5412

By Email

Carmen J. Rodia, Jr.
Environmental Protection Specialist
U.S. EPA, Office of Pesticide Programs,
Registration Division, Insecticide Branch
1200 Pennsylvania Avenue, NW (7504P)
Washington, DC 20460-0001

Re: Tru Prodigy; VetGuard VetIQ Vet Grade

Dear Carmen:

This letter responds to your email dated May 22, 2013 and follows up our meeting on April 30, 2013 with Scott Adcock (President), Cristen Rose and me on behalf of Tru Prodigy, and Lois Rossi, Jeff Hemdon, Marion Johnson, Michelle Knorr (by phone), Richard Gebken and you on behalf of EPA.

From Tru Prodigy's perspective, the objective of the April 30 meeting was to reach a final, mutually acceptable resolution of EPA's concerns with the trade name, "VetGuard." In two letters dated February 12, 2013, your office stated that it had "rescinded" the VetGuard name on Tru Prodigy's EPA-approved products "VetGuard for Dogs" and "VetGuard for Cats" because it had received complaints stating that the name is "false and misleading to the consumer since the product is not restricted to retail sale from only veterinarians."¹ In a subsequent conference call on March 7, 2013 among Richard, you, Cristen and me, Cristen and I explained why, in our view, the VetGuard name could not possibly mislead consumers into believing that sale of the products is restricted to veterinarians. We also emphasized that changing the trade name now would cause irreparable injury to the company. We provided further justification for

¹ In response to a FOIA request filed on behalf of Tru Prodigy for "all complaints or inquiries from third parties about the brand name 'VetGuard' and/or EPA Reg. Nos. 88966-1 or 88966-2," EPA responded that there were "no records" responsive to the request. Tru Prodigy has appealed this no record determination.

Carmin Rodia
May 31, 2103
Page 2

the VetGuard name and the need for a prompt resolution in a letter dated March 21, 2013. In response, your office issued a letter dated April 9, 2013 stating in pertinent part: "Please note that the Agency is not going to pursue any regulatory action related to Tru Prodigy's use of the trade name 'VetGuard' on the referenced products at this time. However, we will be reevaluating our current policy as it applies to the 'VetGuard' trade name, and will keep Tru Prodigy informed of our findings."

In light of the April 3, 2013 letter, Tru Prodigy requested a face-to-face meeting with the Agency because it needed a final determination with respect to the Agency's position on its VetGuard trade name. Based on the April 30 meeting, we understand that the Agency no longer objects to the VetGuard name. We respectfully request that EPA confirm that its concerns with the VetGuard name are now resolved. Having this certainty now is critically important to the company, because it is continuing to invest many millions of dollars per year in marketing and promotion of the VetGuard name, and because the company's two Section 3 VetGuard registrations are time-limited and must be renewed in two years. The company cannot afford to have EPA's approval of those renewed registrations conditioned on the removal of the VetGuard name.

Although the issue of the VetGuard name now appears to be resolved, two new issues were raised at the April 30 meeting. First, you indicated that a comparison of the EPA-approved label for Tru Prodigy's distributor product, VetGuard Plus for Dogs, with Tru Prodigy's labeling for this product, found over 20 "deviations." You declined to identify these "deviations" at the meeting, but your May 22, 2013 email states that a letter detailing your concerns related to the labeling for this product will be issued by the first week of June.

Second, discussion focused on a new print advertisement for the VetGuard Plus for Dogs product that features an endorsement by a veterinarian and also shows the front panel of the respective product labels for small, medium, and large dogs. Two issues regarding this advertisement were raised at the meeting, and your May 22 email requests further explanation regarding these and related items. Although we are somewhat unclear as to the information you are looking for in your May 22 email, we provide additional information regarding these items below:

1. "VETIQ" logo and associated app and "VetGuardPlus" website: "VETIQ™" is an umbrella brand name used for all products (both pesticidal and non-pesticidal) manufactured or formulated by or on behalf of either Tru Prodigy or its corporate affiliate, TruRx. The app enables customers to enter and track expenses and medications for their pets, and can be programmed by the user to provide reminders. Users also can use the app to enter and then print the vaccination history for their pets.

The VetGuardPlus website has a wide range of information regarding pet care and VETIQ products. Certain statements found on the website may be characterized as pesticidal. For example, the website includes the following statements under the heading, "What Is Vet Grade?" "Quality – same quality of products veterinarians recommend"; and "Ingredients – ingredients proven effective." Both of these statements are true and can be readily substantiated.

Carmin Rodia
May 31, 2103
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The statement regarding quality also is discussed further below in the context of the "Vet Grade" definition.

The website also contains certain claims regarding VetGuard Plus for Dogs that are consistent with, and do not substantially differ from, label claims approved by EPA for this product. These claims include: "Shown to kill over 92% of fleas within one day of application"; "Prevents eggs and larvae from becoming adults"; and "Repels new pests from coming in contact with your dog." Additionally, the two active ingredients contained in the product (permethrin and pyriproxyfen) are discussed. Thus, a video on the website describes permethrin as "powerful" and "fast-acting" and the website itself states that fleas exposed to permethrin "become hyperactive and exhibit a 'hot foot' behavior where they will scurry across the animal and then jump off and die." These are true statements supported by efficacy studies submitted or cited by Tru Prodigy, and which are very similar to statements on the website for Bayer's permethrin-containing product, Advantix, as well as the websites of other competitor products. Pyriproxyfen is described as an "Insect Growth Regulator or IGR ... [which] stops the 'next generation' of fleas and ticks from infecting your dog and premises." This statement is also true and consistent with claims approved by EPA for this product.

2. Vet Grade: The term "Vet grade" is defined in both the print advertisement discussed at the April 30 meeting and on VetGuardPlus website in these or similar words: "Vet grade is defined as product quality veterinarians recommend." At the April 30 meeting, there was some discussion regarding this definition. While Tru Prodigy does not believe this definition is objectionable, it is willing to refine it to be more specific for EPA-regulated products. The company proposes the following further clarification: "Vet grade is defined as a product formulated with the same active ingredient in products sold by vets." Thus, for example, both of Tru Prodigy's Section 3 products contain fipronil, the same active ingredient contained in Frontline™, which is sold by veterinarians.

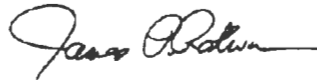
* * *

Tru Prodigy is ready to file applications to add the statements discussed above to the label for these products immediately. Before doing so, however, we wish to ensure that no other amendments to the labels/labeling are required to address all outstanding Agency concerns. Accordingly, we will await your upcoming letter regarding the other label concerns regarding the VetGuard plus for Dogs product before proceeding with label amendments.

Carmin Rodia
May 31, 2103
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Thank you very much.

Sincerely,

A handwritten signature in cursive script, appearing to read "James P. Rathvon".

James P. Rathvon
Cristen S. Rose

cc: Lois Rossi
Erin Koch, Esq.
Michelle Knorr, Esq.
Marion Johnson
Richard Gebken



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Tru Prodigy/88966-1	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Tru Prodigy/VetGuard for Cats	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Tru Prodigy c/o Pyxis Regulatory Consulting 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>Aug. 28, 2013</u>	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of revised label.

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.017 oz.	No. per container 3
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 0.051 fl. oz.	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other on box and on insert in box	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Ann M. Tillman	Title Agent	Telephone No. (Include Area Code) (253) 853-7369	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent	
4. Typed Name Ann M. Tillman		5. Date 9/17/13	

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

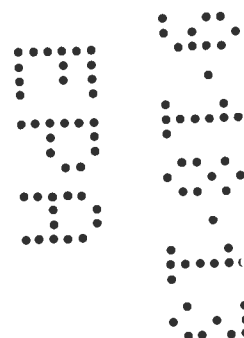
PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
088966-1	Sept. 17, 2013	088966-1.20130916.VetGuard for Cats Label.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.



Signature
Ann M. Tillman
Agent for Tru Prodigy

Sept. 17, 2013
Date



There is an **ELECTRONIC LABEL** for this action

You can use Acrobat to compare the e-label to the previous version (and find the changes). You can also use Acrobat to mark-up the e-label with your comments.

If e-label was submitted via

CD-ROM with paper application

then you will find e-label in

Electronic Label Library

If the e-label is not found in the ELL then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the Front End.

or

If e-label was submitted via

XML E-Submission (no paper)

then you will find e-label in

Documentum

See overview of processing e-labels on other side of this sheet.

If you have any questions on e-labels, please contact one of your division e-label experts:

AD	Willie Abney	308-1689
	Renae Whitaker	308-7003
	Tracy Lantz	308-6415
BPPD		
RD	Tom Harris	308-9423



500 E. Shore Dr. Suite 120 Eagle, Idaho 83616 Ph: (208) 939-8900 Fax: 208-939-3200

January 3, 2012

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Ann Tillman, Mike Kellogg, Leanne Pruett, Ross Gilbert, Janelle Kay, Maryanne Geisbush or Arianna Shorey of Pyxis Regulatory Consulting, Inc. is authorized to act as agent for Tru Prodigy, LLC (EPA Company Number [pending]), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

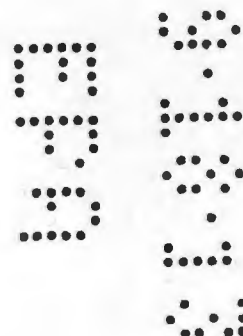
If you have any questions, please do not hesitate to contact me at 208-939-8900 x311.

Sincerely,

Cord Christensen

CEO

cc: Pyxis Regulatory Consulting, Inc.



1. Package Insert
2. Carton (front, back, inside and side panels)
3. [Optional text for front or Optional text for back of cardboard insert if security packaging used]
4. Optional card with tips for use
5. Reminder Stickers
6. Text for back of blister
7. Text for back of pipette (applicator)

Note to reviewer: optional text is placed in brackets

1. Package Insert, Text

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil:.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:.....100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

[Waterproof]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Effective treatment that kills adult fleas which may cause flea allergy dermatitis]

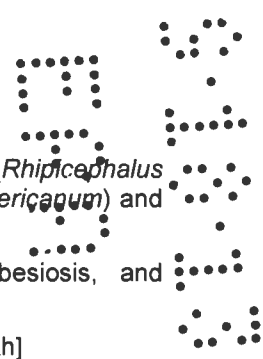
[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, and anaplasmosis]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills adult mosquitoes]



Package Insert, Text

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IF SWALLOWED: Immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Have the product container label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-888-314-8588 for emergency medical treatment information.

HAZARDS TO DOMESTIC ANIMALS

For external use only on cats. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

Side Effects. After applying VetGuard for Cats, check your cat for side-effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea have been reported from grooming after treatment. If you observe these signs or symptoms in your treated cat, contact your veterinarian. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON DOGS OR OTHER ANIMALS.

VetGuard for Cats is approved for use on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks.

VetGuard for Cats keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

Package Insert, Text

Frequency of Application

Monthly application of VetGuard for Cats controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days.

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

Ticks: VetGuard for Cats kills ticks for at least one month. Apply VetGuard for Cats every 30 days to control ticks (larva, nymph and adult) that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis.

Chewing Lice: VetGuard for Cats kills chewing lice for at least one month. Apply VetGuard for Cats every 30 days to control chewing lice.

Mosquitoes: Apply VetGuard for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Use VetGuard for Cats on all cats including breeding, pregnant and lactating queens, and on kittens 8 weeks or older.

A one-spot application is convenient and easy for effective treatment of fleas, ticks, chewing lice, and mosquitoes. Apply VetGuard for Cats when your cat is dry.

VetGuard for Cat is applied at a single point on the surface of the skin between the cat's shoulders and rapidly covers the entire cat by localizing in the hair, on the surface of the skin and in the sebaceous glands.

Soon after coming into contact with a treated cat, fleas, ticks, mosquitoes, and chewing lice are killed. To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:

Package Insert, Text

Remove and Open Package

- 1** Cut along scissor cut line to separate unit



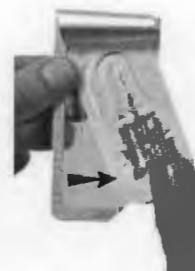
- 2** Turn unit over and cut corner at bulb end



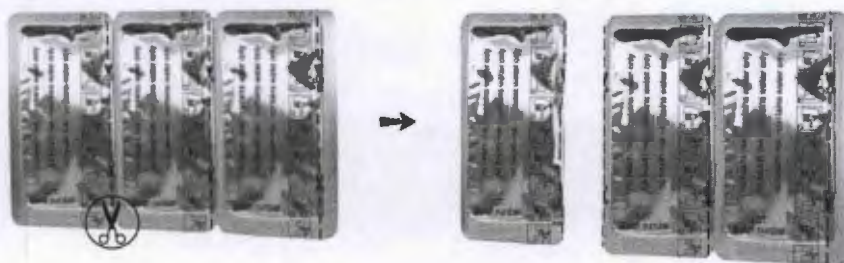
- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



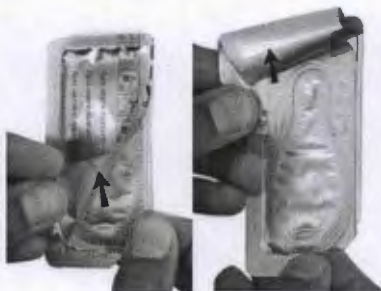
- 1** Cut along scissor cut line to separate unit



- 2** Turn unit over and cut corner at bulb end



- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



Package Insert, Text

Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open.

Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.



PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store unused product in original container only, out of reach of children and animals.

CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of Tru Prodigy. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Tru Prodigy makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither Tru Prodigy, the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages

Package Insert, Text

resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

EPA Reg. No.: 88966-1

[EPA Est. No.:]

Manufactured for:

Tru Prodigy
500 E. Shore Drive, Suite 130
Eagle, ID 83616

[Customer Service: 1-888-314-8588]

[For more information, visit www.VETIQ.com]

[Made in Germany]

[VetGuard for Cats is a registered trade name of Tru Prodigy]

[Optional Bar Code]

2. Carton Text – Front Panel

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil:.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:.....100.0%

Net Contents [3-pak] 0.051 fl. oz. (1.5 mL) (3 tubes containing 0.017 fl. oz. each)

[3 Doses]

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for First Aid and Precautionary Statements.

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

[Waterproof]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Effective treatment that kills fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, and anaplasmosis]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills adult mosquitoes]

[Kills fleas, ticks, chewing lice and mosquitoes]

[3 Month Supply]

[3 Applicators]

[CONTAINS FIPRONIL, SAME ACTIVE INGREDIENT AS PET ARMOR® AND FRONTLINE TOP SPOT™]

[Pet Armour is a registered trademark of FidoPharm, Inc.]

[Frontline and Frontline Top Spot are registered trademarks of Merial.]

[VetGuard for Cats is not manufactured or distributed by Merial or by FidoPharm, Inc.]

FREE APP AT

www.VETIQ.com

VETIQ

vetGuard **FOR**
CATS



2. Carton Text – Back Panel

VETGUARD FOR CATS

[3 Doses]

[Quick-acting]

[Long-lasting]

[Waterproof]

[3 Month Supply]

FREE APP AT

www.VETIQ.com

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE.

Manufactured for:

Tru Prodigy
500 E. Shore Drive, Suite 130
Eagle, ID 83616

[Customer Service: 1-888-314-8588]

EPA Reg. No. 88966-1

EPA Est. No.

[Made in Germany]

[For more information, visit www.VETIQ.com]

[Batch/Lot No.]

[Bar Code]

[VetGuard for Cats is a registered trade name of Tru Prodigy]

VetGuard for Cats can be used on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks. VetGuard for Cats controls fleas, ticks, chewing lice and mosquitoes and keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

DIRECTIONS FOR USE

It is a violation of law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR CAT, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON DOGS OR ON OTHER ANIMALS.**

Side Effects. See package insert for side effects.

To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:

Remove and Open Package

See package insert for opening instructions.

Open Applicator and Apply VetGuard for Cats

Hold upright with foil side away from you and snap applicator tip back to open.



Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.

VETIQ

2. Carton Text - Inside Panel

[3 Month Supply]

READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE.

USE ONLY ON CATS & KITTENS 8 WEEKS AND OLDER

KEEP OUT OF REACH OF CHILDREN

CAUTION

VetGuard for Cats can be used on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks. VetGuard for Cats controls fleas, ticks, chewing lice and mosquitoes and keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

Frequency of Application

Monthly application of VetGuard for Cats controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days.

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

Ticks: VetGuard for Cats kills ticks for at least one month. Apply VetGuard for Cats every 30 days to control ticks (larva, nymph and adult) that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis.

Chewing Lice: VetGuard for Cats kills chewing lice for at least one month. Apply VetGuard for Cats every 30 days to control chewing lice.

Adult Mosquitoes: Apply VetGuard for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store unused product in original container only, out of reach of children and animals.

CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

2. Carton Text –Side Panel

VETIQ

VetGuard for catsCats

[3 Month Supply]

[EPA Reg. No. 88966-1]

[EPA Est. No.]

[Batch/Lot No.]

3. [Optional text for front of cardboard insert if security packaging used]

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil:.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:.....100.0%

Net Contents (one box) [0.051 fl. oz. (1.5 mL), 3 tubes containing 0.017 fl. oz. each, 3 doses]

Net Contents (two boxes) [1.02 fl. oz. (3.0 mL), each box has 3 tubes containing 0.017 fl. oz. each, 6 doses]

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for First Aid and Precautionary Statements.

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

[Waterproof]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Effective treatment that kills fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, and anaplasmosis]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills adult mosquitoes]

[Kills fleas, ticks, chewing lice and mosquitoes]

[3 Month Supply]

[3 Applicators]

FREE APP AT

www.VETIQ.com

EPA Reg. No. 88966-1

EPA Est. No.

Manufactured for:

Tru Prodigy

500 E. Shore Drive, Suite 130

Eagle, ID 83616

[Customer Service: 1-888-314-8588]

[Bar code]

[For more information, visit www.VETIQ.com]

VETIQ

vetGuard FOR
CATS



3. [Optional text for back of cardboard insert if security packaging used]

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil:.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:.....100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[Quick-acting]

[Long-lasting]

[Waterproof]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Effective treatment that kills adult fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, and anaplasmosis]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills adult mosquitoes]

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IF SWALLOWED: Immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Have the product container label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-888-314-8588 for emergency medical treatment information.

HAZARDS TO DOMESTIC ANIMALS

For external use only on cats. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using **ANY** pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

Side Effects. After applying VetGuard for Cats, check your cat for side-effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea have been reported from grooming after treatment. If you observe these signs or symptoms in your treated cat, contact your veterinarian. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR PET, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON DOGS OR OTHER ANIMALS.**

VetGuard for Cats is approved for use on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks.

VetGuard for Cats keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

Frequency of Application

Monthly application of VetGuard for Cats controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days.

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

Ticks: VetGuard for Cats kills ticks for at least one month. Apply VetGuard for Cats every 30 days to control ticks (larva, nymph and adult) that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis.

Chewing Lice: VetGuard for Cats kills chewing lice for at least one month. Apply VetGuard for Cats every 30 days to control chewing lice.

Mosquitoes: Apply VetGuard for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Use VetGuard for Cats on all cats including breeding, pregnant and lactating queens, and on kittens 8 weeks or older.

A one-spot application is convenient and easy for effective treatment of fleas, ticks, chewing lice, and mosquitoes. Apply VetGuard for Cats when your cat is dry.

VetGuard for Cat is applied at a single point on the surface of the skin between the cat's shoulders and rapidly covers the entire cat by localizing in the hair, on the surface of the skin and in the sebaceous glands.

Soon after coming into contact with a treated cat, fleas, ticks, mosquitoes, and chewing lice are killed. To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:

Remove and Open Package

- 1** Cut along scissor cut line to separate unit



- 2** Turn unit over and cut corner at bulb end



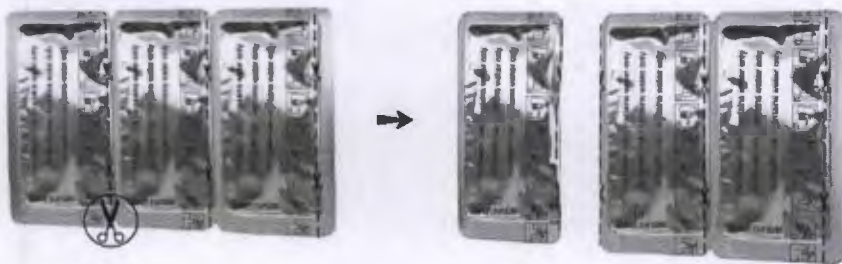
- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



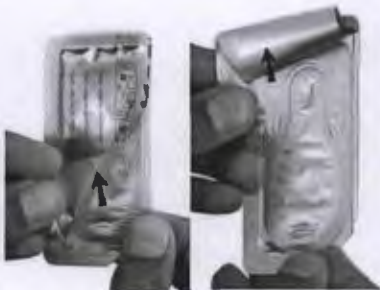
- 1** Cut along scissor cut line to separate unit



- 2** Turn unit over and cut corner at bulb end



- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open.

Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.



PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store unused product in original container only, out of reach of children and animals.

CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of Tru Prodigy. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Tru Prodigy makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither Tru Prodigy, the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

VETIQ

4. [Optional Card with Tips, Text]

[Optional marketing claims]

[VetGuard for Cats]

[See other side for stickers to remind you it's time to reapply VetGuard for Cats.]

[Some Tips and Other Information for Using VetGuard for Cats]


[Treat dogs and cats separately and only with the proper dose of VetGuard for Dogs or VetGuard for Cats.]

[Follow the label instructions for how to apply and be sure that VetGuard for Cats is applied to the skin, not on top of the fur and not near the collar. Removing the collar before application may help to prevent the collar from absorbing the VetGuard dose.]

[Apply VetGuard for Cats when your cat is dry. Make sure you apply all of the dose that is in the applicator.]

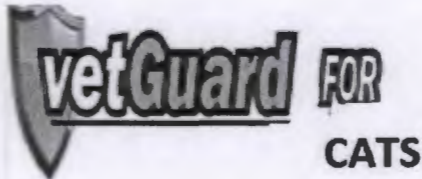
[Even indoor cats need flea and tick control if other household pets bring fleas into the home.]

[Fleas have many life stages and serious infestations can take up to 3 applications every 30 days for control. In fact, the flea life-cycle in the home can last as long as 21 days.]

The logo for VETIQ, featuring the word "VETIQ" in a bold, sans-serif font. The letters are white and set against a dark, rounded rectangular background. The logo is positioned on the left side of the page, with a vertical line to its left.

5. Text for Reminder Stickers

VETIQ



[Reminder: It's time to repurchase VetGuard for Cats!]

Use these stickers to remind you when to apply and to purchase VetGuard for Cats.

The first time you treat your cat, peel off the sticker and place on your calendar that day. To remind you when the next application is due, place the other two stickers on your calendar 1 and 2 months after the first application.

FREE APP AT
[www.VETIQ.com]

[For Customer Service call 1-888-314-8588.]

[For more information, visit www.VETIQ.com]

[For more information, visit www.xxxxx.com]



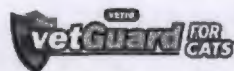
[Optional Bar code]

6. Text for Back of Blister

Pictogram of Back of Blister With Opening Instructions



6. Text for Back of Blister



ONLY FOR CATS AND KITTENS

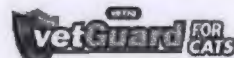
9.7% FIPRONIL

0.017 fl. oz (0.5 mL)

EPA Reg. No. 88966-1

KEEP OUT OF REACH OF CHILDREN

CAUTION: see full label for additional instructions
and precautions before using



ONLY FOR CATS AND KITTENS

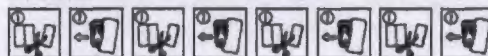
9.7% FIPRONIL

0.017 fl. oz (0.5 mL)

EPA Reg. No. 88966-1

KEEP OUT OF REACH OF CHILDREN

CAUTION: see full label for additional instructions
and precautions before using



ONLY FOR CATS AND KITTENS

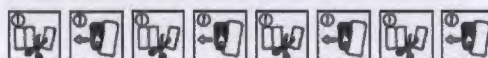
9.7% FIPRONIL

0.017 fl. oz (0.5 mL)

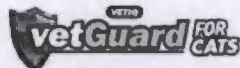
EPA Reg. No. 88966-1

KEEP OUT OF REACH OF CHILDREN

CAUTION: see full label for additional instructions
and precautions before using



7. Text for back of pipette (applicator)



ONLY FOR CATS AND KITTENS

9.7% FIPRONIL 0.017 fl. oz (0.5 mL)

EPA Reg. No. 88966-1

See full label for additional instructions
and precautions before using

KEEP OUT OF REACH OF CHILDREN

CAUTION

KEEP OUT OF REACH OF

CHILDREN

CAUTION: See full label for additional instructions and precautions before using

Only for Cats & Kittens

VetGuard for Cats

~~EPA Reg. No. 88966-1~~
~~Lot/Batch No.~~
~~0.017 fl. oz. (0.5 mL)~~
~~9.7% Fipronil~~

~~7. Text for back of pipette (applicator)~~

~~KEEP OUT OF REACH OF CHILDREN~~

~~CAUTION: See full label for additional instructions and precautions before using~~

~~Only for Cats & Kittens~~

~~VetGuard for Cats~~

~~EPA Reg. No. 88966-1~~

~~Lot/Batch No.~~

~~0.017 fl. oz. (0.5 mL)~~

~~9.7% Fipronil~~

Rodia, Carmen

From: Ann Tillman [Ann@PyxisRC.com]
Sent: Thursday, September 12, 2013 2:44 PM
To: Rodia, Carmen
Cc: Gross, Rosalind
Subject: EPA Reg. No. 88966-1 VetGuard for Cats
Attachments: 20130912 VetGuard for Cats Public Data Matrix.revised.sent by email.pdf; 20130912 VetGuard for Cats Agency Data Matrix.revised.sent by email.pdf

Carmen,

Per Rosalind's email, I revised the data matrices for VetGuard for Cats to include the MRIDS for CRP studies. Two pdf files are attached. Please acknowledge receipt. Thanks.

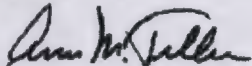
Ann

*Ann M. Tillman, Ph.D.
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332
Office (253) 853-7369
Fax (253) 853-5516
Email Ann@PyxisRC.com*

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

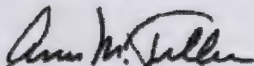
DATA MATRIX

Date September 12, 2013			EPA Reg. No./File Symbol 88966-1		Page 1 of 7
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748			Product VetGuard for Cats		
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	48755401	Tru Prodigy	OWN	
830.1600	Description of Materials Used to Produce the Product	48755401	Tru Prodigy	OWN	
830.1620	Description of Production Process				Not required ¹
830.1650	Description of Formulation Process	48755401	Tru Prodigy	OWN	
830.1670	Discussion of Formation of Impurities	48755401	Tru Prodigy	OWN	
830.1700	Preliminary Analysis				Not Required ²
830.1750	Certified Limits	48755401	Tru Prodigy	OWN	
830.1800	Enforcement Analytical Method	48755401	Tru Prodigy	OWN	
830.6302	Color	48755402	Tru Prodigy	OWN	
830.6303	Physical State	48755402	Tru Prodigy	OWN	
830.6304	Odor	48755402	Tru Prodigy	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions				Not Required ³
830.6314	Oxidation/Reduction: Chemical Incompatibility	48755402	Tru Prodigy	OWN	
830.6315	Flammability	48755402	Tru Prodigy	OWN	
Signature 			Name and Title Ann M. Tillman, Consultant		Date September 12, 2013

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

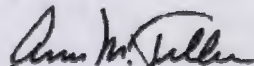
Date September 12, 2013			EPA Reg. No./File Symbol 88966-1		Page 2 of 7
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748			Product VetGuard for Cats		
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6316	Explosibility	48755403	Tru Prodigy	OWN	Waiver ⁴
830.6317	Storage Stability	49109201	Tru Prodigy	OWN	
830.6319	Miscibility				Not required ⁵
830.6320	Corrosion Characteristics	49109201	Tru Prodigy	OWN	
830.6321	Dielectric Breakdown Voltage				Not required ⁶
830.7000	pH	48755402	Tru Prodigy	OWN	
830.7050	UV/Visible Absorption				
830.7100	Viscosity	48755402	Tru Prodigy	OWN	
830.7200	Melting Point/Melting Range				Not required ⁷
830.7220	Boiling Point/Boiling Range				Not required ⁸
830.7300	Density/Relative Density/Bulk Density	48755402	Tru Prodigy	OWN	
830.7370	Dissociation Constants in Water				Not required ⁸
830.7520	Particle size, fiber length, diameter distribution	48755403	Tru Prodigy	OWN	Waiver ⁸
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Not required ⁸
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
Signature 			Name and Title Ann M. Tillman, Consultant		Date September 12, 2013

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date September 12, 2013		EPA Reg. No./File Symbol 88966-1		Page 3 of 7	
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748		Product VetGuard for Cats			
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550
830.7840	Water Solubility: Column Elution Method; Shake Flask Method				Not required ⁸
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure				Not required ⁸
870.1100	Acute Oral Toxicity: Rat	43577705 43951703		OLD OLD	
870.1200	Acute Dermal Toxicity: Rat	43577706		OLD	
870.1300	Acute Inhalation Toxicity: Rat	43577707		OLD	
870.2400	Primary Eye Irritation: Rabbit	43577708		OLD	
870.2500	Primary Dermal Irritation	43577709		OLD	
870.2600	Dermal Sensitization	43577710		OLD	
Signature 			Name and Title Ann M. Tillman, Consultant		Date September 12, 2013

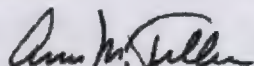
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Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748			Product VetGuard for Cats		
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7200	Companion Animal Safety	Cite-all		PAY	
810.3300	Product Performance	Cite-all		PAY	
US 16 CFR § 1700	Child Resistant Packaging Study	48755301 49179701 49179702 49179703	Tru Prodigy Tru Prodigy Tru Prodigy Tru Prodigy	PER PER PER PER	
Fipronil Generic and Product Specific Data Requirements					
Tru Prodigy will make offers-to-pay to the following companies on the fipronil data submitters list of April 8, 2013.					
		Cite-All	Syngenta Crop Protection LLC	PAY	
		Cite-All	The Scotts Company	PAY	
		Cite-All	Bayer Cropscience LP	PAY	
		Cite-All	Bayer Environmental Science	PAY	
		Cite-All	Whitmire Micro-Gen Research Laboratories	PAY	
		Cite-All	Pfizer, Inc.	PAY	
		Cite-All	Virbac AH, Inc.	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date September 12, 2013

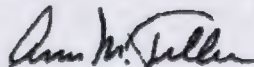
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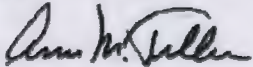
DATA MATRIX

Date September 12, 2013			EPA Reg. No./File Symbol 88986-1		Page 5 of 7
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748			Product VetGuard for Cats		
Ingredient Flupronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Sergeant's Pet Care Products, Inc.	PAY	
		Cite-All	The Hartz Mountain Corp.	PAY	
		Cite-All	Reckitt Benckiser LLC	PAY	
		Cite-All	Cheminova A/S	PAY	
		Cite-All	J. J. Mauget Co.	PAY	
		Cite-All	BASF Corp.	PAY	
		Cite-All	Chemsico	PAY	
		Cite-All	Makhteshim Chemical Works Ltd.	PAY	
		Cite-All	Gharda Chemicals Limited	PAY	
		Cite-All	Control Solutions Inc.	PAY	
		Cite-All	Virbac	PAY	
		Cite-All	Combat Insect Control Systems	PAY	
		Cite-All	Pyrethroid Working Group	PAY	
		Cite-All	Merial Limited	PAY	
		Cite-All	Spray Drift Task Force	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date September 12, 2013

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DATA MATRIX

Date September 12, 2013			EPA Reg. No./File Symbol 88966-1		Page 4 of 7
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748			Product VetGuard for Cats		
Ingredient Fipronil (CAS No. 120088-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Cheminova Inc.	PAY	
		Cite-All	Outdoor Residential Exposure Task Force	PAY	
		Cite-All	Agricultural Reentry Task Force	PAY	
		Cite-All	Ambrands	PAY	
		Cite-All	Innovative Pest Control Products	PAY	
		Cite-All	FIFRA Endangered Species Task Force	PAY	
		Cite-All	Irvita Plant Protection N.V.	PAY	
		Cite-All	Residential Exposure Joint Venture	PAY	
		Cite-All	Agricultural Handlers Exposure Task Force	PAY	
		Cite-All	Ceva Animal Health, LLC	PAY	
		Cite-All	Sharda USA LLC	PAY	
		Cite-All	Gharda Generics, Inc.	PAY	
		Cite-All	Fidopharm, Inc.	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date September 12, 2013

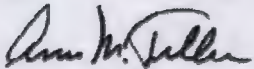
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DATA MATRIX

Date September 12, 2013			EPA Reg. No./File Symbol 88966-1		Page 7 of 7
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748			Product VetGuard for Cats		
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Norbrook Laboratories, Ltd.	PAY	
		Cite-All	Loradochem, Inc.	PAY	
		Cite-All	Linouvel, Inc.	PAY	
		Cite-All	Zhejiang Hisun Pharmaceuticals Co., Ltd.	PAY	
		Cite-All	Argite - Fipronil LLC	PAY	
		Cite-All	Firponex Solutions Inc.	PAY	
		Cite-All	Virbac S. A.	PAY	
		Cite-All	Raymat Materials Inc.	PAY	
		Cite-All	Chanelle Pharmaceuticals Manufacturing	PAY	
		Cite-All	Horizon Valley Generics, Inc.	PAY	
		Cite-All	American Vet Sciences, LLC	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date September 12, 2013

Endnotes for Data Matrix for VetGuard for Cats

-
- ¹ **830.1620** – These data are not required for the registration of an end-use product. See 830.1650 for formulation process information.
- ² **830.1700** – This product does not consist solely of the technical grade active ingredient (TGAI) and is not produced by an integrated system, therefore, per OPPTS 830.1700, these data are not required.
- ³ **830.6313** – These data are not required for registration of an end-use product.
- ⁴ **830.6316** - Tru Prodigy requested a waiver from this data requirement because fipronil does not have the chemical bonds or functional groups associated with explosive chemicals. There are no potentially explosive ingredients in VetGuard for Cats (refer to the CSF for VetGuard for Cats). EPA accepted this waiver in a review dated July 17, 2012 (DP Barcode 401382).
- ⁵ **830.6319** - This data requirement is required when the product is an emulsifiable liquid and to be diluted with petroleum solvents. VetGuard for Cats is not an emulsifiable concentrate and its labeling does not allow it to be diluted with petroleum solvents; therefore this data requirement is not applicable to VetGuard.
- ⁶ **830.6321** - These data are required if the product is an end-use product and is applied around electrical equipment. VetGuard is not to be applied around electrical equipment; therefore this data requirement is not applicable.
- ⁷ **830.7200, 830.7220, 830.7370, 830.7550-7570, 830.7840-7860, 830.7950** – These data are not required for registration of an end-use product.
- ⁸ **830.7520** – Tru Prodigy requested a waiver for this data requirement for VetGuard because the product is not a fibrous material and is not a water-insoluble material. EPA did not require this study as a condition of registration (see EPA review dated July 17, 2012; DP Barcode 401382).

Rodia, Carmen

From: Ann Tillman [Ann@PyxisRC.com]
Sent: Thursday, September 05, 2013 12:35 PM
To: Rodia, Carmen
Subject: TruProdigy VetGuard EPA Reg. Nos. 88966-1 and 88966-2
Attachments: VETIQ BRAND STRATEGY.pdf; True Science Brand Architecture 0813.pdf

Hi, Carmen,

I promised to send you an explanation from Tru Prodigy on the use of the VetIQ brand on their packaging. Tru Prodigy explains their product branding in the attached documents. A good example of "brands" is Proctor & Gamble. The parent company, Proctor & Gamble, is a brand that covers a multitude of products. Examples include Cover Girl, Gillette, Oral-B and many others. Under each brand is a multitude of products, generally in one category. Under the VetIQ brand, Tru Science (who fully owns the subsidiary Tru Prodigy) sells products to make a pet's life better (flea & tick, supplements, prescription medications). More examples are found in their description of the brand architecture, but VetIQ is their brand that covers a range of products.

Please let me know if you have any questions.

Ann

*Ann M. Tillman, Ph.D.
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332
Office (253) 853-7369
Fax (253) 853-5516
Email Ann@PyxisRC.com*

VETIQ BRAND STRATEGY

VetIQ is a brand developed to provide an edge in an increasingly competitive pet product marketplace. It was developed to help customers understand what they can expect from our products, and it differentiates our offerings from our competitors'. VetIQ was also derived to help the consumer easily recognize we are a pet products brand.

The foundation of our brand is the logo. Because it's a potential benefit to the consumer, using the logo on packaging, websites, promotional materials, and other advertising is imperative to it's usefulness in the marketplace, and to the consumer.

Our company mission is to provide quality pet products at prices people can afford. We desire to provide the best information possible so that pet owner's can make informed decisions for their pets. For this reason we developed the VetIQ brand strategy including brand messaging, advertising, distribution, etc. In order for this strategy to be affective we need consistent, strategic messaging of our company's products in all forms of media.



Brand Architecture

True Science, LLC is a holding company that sells quality pet products under a number of brands, at prices consumers can afford. These include VetIQ™ and Betsy Farms™ – two brands currently available for sale at retailers nationwide; and Lil' Tex Ranch™ and Delightibles™ – two brands that are under development and will ship in 2014. True Science, LLC is similar to companies like Procter & Gamble and Reckitt Benckiser that don't merchandise products under the company name, but rather under separate brands, like as Gillette, Olay, Crest, Herbal Essences, Lysol, and others. More information with regards to True Science can be found on our corporate website, www.truescience.com. Tru Prodigy is a wholly owned subsidiary of True Science.

VetIQ™ is the flagship brand for True Science, LLC. VetIQ™ offers pet prescription medications, over-the-counter flea & tick preventatives, and other health and wellness supplements for America's pets, at savings to other branded alternatives.

VetIQ™ products include VetGuard Plus® Flea & Tick control, Minties® Dental Treats, VetIQ™ Hip & Joint, VetIQ™ Vitamin Chews, VetIQ™ Skin & Coat, VetIQ™ Pill Treats, TruProfen™ and Heart Shield™ Plus. Each product is designed to address a particular health benefit. Retailers that carry VetIQ™ products include Walmart, Sam's Club, Kroger, Kmart, Costco and Rite Aid. For more information, please visit www.VetIQ.com.

In Summer 2013, True Science launched a new brand of products, Betsy Farms™. Betsy Farms™ products are different from VetIQ products in that they are simple *dog treats* without a particular functional benefit. Market research and conventional wisdom indicate that consumers desire brands that simplify the buying decision, and that brands should address wants and needs that are unique and meaningful to them. Our Delightibles™ brand, planned for 2014 launch, will provide quality *cat treats*, made in the USA.

Each of the brands that True Science employs a token brand strategy. For example, VetIQ products VetGuard Plus, Minties, Hip & Joint, etc., have the VetIQ logo on the principle display panel of the package or in other consumer communications. May other brands do this including Kraft (Kraft Jello, Kraft Oreo, and Kraft Velveeta), Gillette (Gillette Fusion, Gillette Venus, and Gillette Mach3), Crest (Crest Pro Health, Crest White Strips, Crest Scope Mouthwash). This provides a common brand for products within the line and is meaningful to consumers. Consumers have learned to trust the VetIQ brand name. As they are happy with one product in the VetIQ™ line, they may have interest in others. Marketing VetIQ™ in this way provides a halo effect – promoting one product raises awareness and trial of others.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Wednesday, August 28, 2013

CERTIFIED MAIL: (Article Number 7008 3230 0000 9482 3630)

OPP Decision Number: D-481141

Ms. Ann M. Tillman, Ph.D.
Regulatory Agent for Tru Prodigy
c/o Plyxis Regulatory Consulting, Inc.
4110 136th Street NW
Gig Harbor, WA 98332-9122

Subject: Data Deficiency
EPA Registration Number: 88966-1
Product Name: VETGUARD FOR CATS
Application Date: July 19, 2013
EPA Receipt Date: July 22, 2013

Dear Ms. Tillman:

The Agency has received and completed its in-depth review of the subject application and has determined that it is incomplete. This letter is a written notification of the deficiencies found and identifies your options under 40 CFR §152.105 and section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), also known as the Pesticide Registration Improvement Renewal Act (PRIA 3). Your options under 40 CFR §152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR §152.105:

Pursuant to 40 CFR §152.105, you are allowed 75 days from the date of this letter ending on Monday, November 11, 2013, to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days, or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. The noted deficiencies for the referenced R340 amendment; non-fast track; review with RD application are as follows:

1. Throughout the subject master label, there is newly proposed text indicating the placement of a "VETIQ" logo and associated generic text related to a free smart phone app. The referenced logo and smart phone app were only briefly discussed with your client; however, they were never reviewed or approved by the Agency for use on the subject master label. As such, your client must state why the proposed generic text, logo, and smart phone app information is being added to the subject master label at this time. If this specific information is not submitted to the Agency for consideration, the "VETIQ" logo and all of the associated generic text related to the free smart phone app will need to be removed from the subject master label. Further review of this application cannot be made until this deficiency has been resolved.

2. The newly added label statement "**MADE IN THE USA**" must be truthful as specified in 40 CFR §152.43. As you know, the accepted basic formulation for this product states that this product is currently only formulated in Germany. As per your conversation with Carmen Rodia on August 28, 2013, all marketing statements listed on the subject master label can only be made if they are based on the accepted basic formulation. Therefore, the newly added label statement "**MADE IN THE USA**" must be deleted from the subject label. Further review of this application cannot be made until this deficiency has been resolved.

Section 33 of FIFRA/PRIA 3:

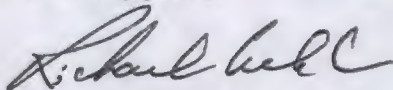
This application is also subject to a deadline for making a determination on the application under section 33 of FIFRA, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on December 12, 2013. As a result, you have to respond to the deficiencies noted above with one of the following three (3) options:

1. **Withdraw the application:** You may notify us no later than December 5, 2013, that you are withdrawing your application. As noted above, withdrawal concludes the Agency's review of your application; however, you may resubmit your application after the noted deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
2. **Not respond:** If you do not respond to the Agency, as specified in detail above, on or before December 5, 2013, the Agency will administratively withdraw your application.
3. **Correct application deficiencies:** You must revise the subject master label as described in detail above and submit a further updated master label to the Agency for use in out-processing this application.

Should you wish to add/retain a reference to the company's website on your label, please be aware that the website becomes labeling under FIFRA, and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not be substantially differ from those claims approved through the registration process. Therefore, should the Agency find, or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

Please respond to this letter by or before **November 11, 2013**, by contacting either Mr. Carmen J. Rodia, Jr. at 703-306-0327 or via e-mail at Rodia.Carmen@epa.gov or Mr. Richard J. Gebken at 703-305-6701 or via e-mail at Gebken.Richard@epa.gov directly during the hours of 9:00 am to 5:00 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely yours,



Richard J. Gebken,
Product Manager (10)
Insecticide Branch,
Registration Division (7504P)

Memorandum

(carmen)

Date: 08/07/13

To: PT 10, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:

- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 05, 2013




OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

PYXIS REGULATORY CONSULTING, LLC
TRU PRODIGY
4110 136TH ST. NW
GIG HARBOR, WA 98332

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 22-JUL-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3				  	
S:	938529		Resubmission:		<input type="radio"/> Yes <input checked="" type="radio"/> No
Regulatory Type:	Product Registration - Section 3		Fee For Service:	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Application Type:	Amendment		Billable:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Company:	88966 TRU PRODIGY		V		
Risk Manager:	Registration Division, Risk Management Team 10				
Product #:	88966-1	Product Name:	VETGUARD FOR CATS		
Override#:					
Me Too Section3:	85331-2	Me Too Product Name:	FIPAIRA FOR CATS		
Application Date:	19-Jul-2013	ie	OPP Rec'vd Date:	22-Jul-2013	ie
Front End Date:	22-Jul-2013	ie	Risk Manager Send Date:		ie
FFS Due Date:			Negotiated Due Date:		
OPP Target Date:					
Fast Track:	<input type="checkbox"/>		New Ingredient:	<input type="checkbox"/>	
Receipt Description:			View/Edit		
Amendment of registration requiring data review			New Ingredient Request Date: <input type="text"/>		
			New Ingredient Received Date: <input type="text"/>		
Form A:	<input type="checkbox"/>		Signature Date:	<input type="text"/>	
Form B:	<input type="checkbox"/>		Signature Date:	<input type="text"/>	

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4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

July 19, 2013

OVERNIGHT DELIVERY

Richard Gebken (PM 10)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

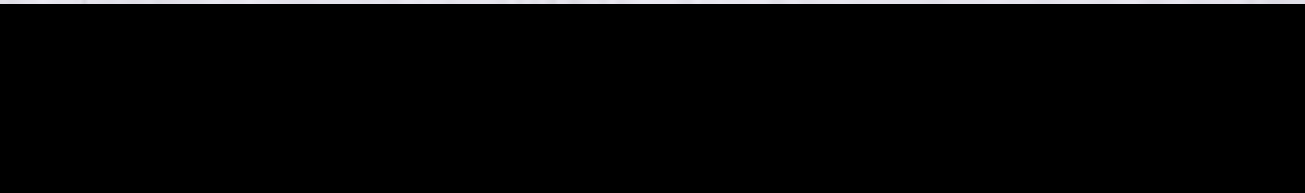
RE: Tru Prodigy
VetGuard for Cats (EPA File Symbol 88966-1)
Application to Amend Pesticide Registration
PRIA Category R340 (Primary Application)

Dear Mr. Gebken,

On behalf of Tru Prodigy, we are submitting an application to amend the registration of VetGuard for Cats to add an additional manufacturing site. This application is tied to the secondary application to amend the registration of VetGuard for Dogs (EPA Reg. No. 88966-2).

This amendment would allow packaging to be done at Klocke of America (KOA) in Fort Myers, FL in addition to the current location in Germany. KOA conducted limited child resistant package testing with CRP made at the Florida as agreed upon at a meeting between KOA and EPA in November 2012. The new data are submitted with this amendment.

Minor product label changes were made to reflect the location of the new manufacturer and to include the VetIQ logo, per previous discussions between EPA and Tru Prodigy.



In support of this application, we submit the following documents:

1. Application for an Amended Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4) dated July 19, 2013

Claimed confidential by submitter

3. One (1) copy of the revised label with changes tracked
4. Three (3) copies of the revised label with changes accepted
5. A CD containing an electronic version of the labels
6. Certification with Respect to Label Integrity
7. Agency Internal Use Copy of the Data Matrix
8. Public File Copy of the Data Matrix
9. Certification with Respect to Citation of Data (EPA Form 8570-34)
10. Child Resistant Packaging Certification
11. Copy of the PRIA payment from pay.gov
12. Copy of this letter with CBI redacted
13. Copy of the cover letter for VetGuard for Dogs, the secondary application
14. Letter of authorization from sponsor of CRP testing
15. Letter of Authorization from Tru Prodigy
16. Product Specific Data (3 copies each):

49179701

Volume 1	US 16 CFR § 1700	Novosad, M. Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 0.5 mL, 0.67 mL and 4.02 mL Capacity. Report Number KOA-201302. May 16, 2013 (Child 12-068, 13-018; Adult 12-069, 13-018).
Volume 2	US 16 CFR § 1700	Tillman, A. M. Overview of Child Resistant Packaging Studies: Thermoforme Blister Pack for Pipettes of 0.5 mL, 0.67 mL and 4.02 mL Capacity. Report Number KOA-201303. June 11, 2013
Volume 3	US 16 CFR § 1700	Novosad, M. Child Resistant Packaging Test Summary Report: Thermoforme Blister Pack for Pipettes of 0.5 mL, 0.67 mL and 4.02 mL Capacity. Report Number KOA-201301. May 16, 2013 (Child 12-068, 13-018; Adult 12-069, 13-018).

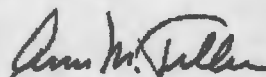
49179702

49179703

Tru Prodigy believes this application falls under Category R340 (54: Amendment requiring data review within RD). The fee due which has been paid is \$3,607 with a PRIA decision time line of 4 months.

We trust you will find this application complete. However, please feel free to contact me by email at Ann@PyxisRC.com or by phone ((253) 853-7369) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures

Decision Information for 88966-1

Decision Seq: 481141
Action Code: R340,AMENDMENT;NON-FAST TRACK;REVIEW WITHIN RD, E.G. I ...

Decision Status

Tracking

Create Resubmission

FFS Letters

Waiver Documentation

Action Code History

Secondary Decision

FFS Start Date: 12-Aug-2013
Tentative Ind: No
Start/Stop Clock
FQPA Clock:

Due Date: 12-Dec-2013
75-Day Due Date:
Days Elapsed:

OPP Target Due Date:
21-Day Due Date: 12-Aug-2013
FFS Original Decision: ...

Negotiated Due Date:
45-Day Due Date: 26-Sep-2013

Registrant:
Predecisional Due Date: 27-Nov-2013

Response Due Date:

Current Status: PENDING (23-Jul-2013)

75 Day Letters
45/90 Day Screen
Primary Decisions

FFS Negotiated Due Dates
OPP Target Due Date
Decision Comments
Payment
Unmatched Payments

Decision Ownership
Receipts
Data Package
Reduced Risk
Meetings & Milestones
FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 938529	Rodia, Carmen	88966-1	12-Dec-2013	PENDING
Amendment to add new establishment facility and to revise basic CSF.				

Viewing Record 1 of 1

58

21-Day Screen of Amendment
(Completed by Contractor)

21-day Expires on 8-12-13

Document Part Of: 88966-1
MRID, If Any: 491797

Per TIAB 8/6/13 the inserts are fine Rachel
Content Screen: Recommended to
Pass/Fail

11-3 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Document returned to:

STEPHEN SCHABER

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 7-22-13

Experts In-Processing Signature: B.B. Date 7-24-13 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>88966-1</u>		EPA Receipt Date: <u>7-22-13</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
			X			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments: Studies passed 11-3 review
491797.

Fail

Inerts Not approved - see Inert Status Form

8/5/13 - An e-mail was sent to the registrant regarding inert issues and a study deficiency.

- Received study corrections

8/6/13 - Sent a follow up e-mail regarding the inerts on the CSF which were not found.

- Inert deficiencies were not addressed.

Please see e-mails

tu

Draft rejection letter₂

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, **to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A531, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Jackson, Tracy

From: Jackson, Tracy
Sent: Tuesday, August 06, 2013 7:21 AM
To: 'Ann Tillman'
Subject: Inert issues (88966-1 and 88966-2)
Attachments: Inert Status 3.doc

Dear Ms. Tillman,

The applications 88966-1 and 88966-2 are due this morning, so when you receive the information on the inerts please send them to the appropriate Product Manager, and be sure to include Steve Schaible, schaible.steve@epa.gov on the correspondence as well. I apologize for any inconvenience.

Thank you
Tracy Jackson

From: Jackson, Tracy
Sent: Monday, August 05, 2013 9:07 AM
To: 'Ann@PyxisRC.com'
Subject: FW: Study Deficiency (88966-1)

Dear Ms. Tillman,

The Confidential Statement of Formula review is complete. There are two inerts that were not found in the EPA database. Please see attachment.

Thank you

Tracy Jackson

EPA Contractor
703-308-7227
2777 S. Crystal Drive
Arlington, VA 22202

From: Jackson, Tracy
Sent: Monday, August 05, 2013 7:16 AM
To: 'Ann@PyxisRC.com'
Subject: Study Deficiency (88966-1)

Dear Ms. Tillman,

I am contacting you regarding your submission in support of **VetGuard for Dogs (88966-1)**. There was a deficiency found in one of the studies submitted.

Study deficiency:

Study volume 2, Overview of Child Resistant Packaging Studies. Pages 18 and 24 are illegible due the poor quality of the photocopying.

Please send corrected pages to jackson.tracy@epa.gov

The confidential statement of formula for this application is under review. You will be contacted at a later date if any deficiencies are found.

Thank you

Tracy Jackson
EPA Contractor
703-308-7227
2777 S. Crystal Drive
Arlington, VA 22202

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EPA Contractor
703-308-7227
2777 S. Crystal Drive
Arlington, VA 22202



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 23, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-481141
EPA File Symbol or Registration Number: 88966-1
Product Name: VETGUARD FOR CATS
EPA Receipt Date: 22-Jul-2013
EPA Company Number: 88966
Company Name: TRU PRODIGY

ANN TILLMAN
PYXIS REGULATORY CONSULTING, LLC
TRU PRODIGY
4110 136TH ST. NW
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340

AMENDMENT;NON-FAST TRACK;REVIEW WITHIN RD, E.G. PRECAUTIONARY LABELING;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Teresa Downs
Front End Processing Staff

Information Technology & Resources Management Division

Fee for Service

{9385290~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☐ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 10

Receipt No.

S- 938529

EPA File Symbol/Reg. No.

88966-1

Pin-Punch Date:

7/22/2013

- ☐ This item is NOT subject to FFS action.

Action Code:

Requested: R340

Granted: R340

Amount Due: \$ 3,617. ^{ce}

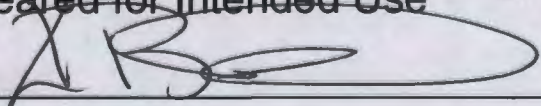
Parent/Child Decisions:

Parent: 88966-1

Child: 88966-2

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: 

Date: 7-23-13

Remarks:

Receipt for Section 3

S: 938529

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 88966 TRU PRODIGY V



Risk Manager: Registration Division, Risk Management Team 10

Product #: 88966-1 Product Name: VETGUARD FOR CATS

Override#

Me Too Section3: 65331-2 Me Too Product Name: FIPAIRA FOR CATS

Application Date: 19-Jul-2013  OPP Rec'd Date: 22-Jul-2013 

Front End Date: 22-Jul-2013  Risk Manager Send Date: 

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

Amendment of registration requiring data review

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

New Ingredient Request Date:

New Ingredient Received Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study
CSF

View/Edit

-----Original Message-----

From: paygovadmin@mail.doc.twai.gov [mailto:paygovadmin@mail.doc.twai.gov]

Sent: Thursday, July 18, 2013 3:58 PM

To: Ann Tillman

Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions or you wish to cancel this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@cleve.frb.org.

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 25BK4GJG

Agency Tracking ID: 74478404210

Transaction Type: Sale

Transaction Date: Jul 18, 2013 3:58:19 PM

Account Holder Name: Steven Anderson

Transaction Amount: \$3,607.00

Billing Address: 500 E Shore Drive

Billing Address 2: Suite 120

City: Eagle

State/Province: ID

Zip/Postal Code: 83616

Country: USA

Card Type: AmericanExpress

Card Number: *****1139

Decision Number:

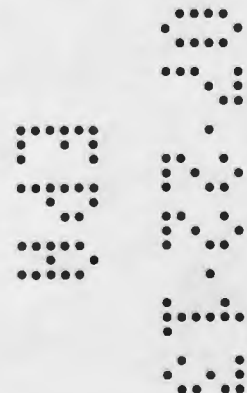
Registration Number: 88966-1

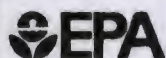
Company Name: Tru Prodigy, LLC

Company Number: 88966

Action Code: R340

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Tru Prodigy/88966-1	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Tru Prodigy/VetGuard for Cats	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Tru Prodigy c/o Pyxis Regulatory Consulting 4110 138th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label amendment to alternate manufacturing sites requiring review of data within RD (PRIA category R340; primary application).

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted	If "Yes" Unit Packaging wgt. 0.017 oz.	No. per container 3	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Glass
					<input type="checkbox"/> Paper
					Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 0.051 fl. oz.		5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other on box and on insert in box			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Ann M. Tillman	Title Agent	Telephone No. (Include Area Code) (253) 853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Ann M. Tillman	5. Date 7/19/13	

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

July 19, 2013

OVERNIGHT DELIVERY

Richard Gebken (PM 10)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

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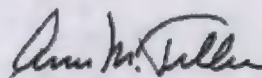
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16. Product Specific Data (3 copies each):

Volume 1	US 16 CFR § 1700	Novosad, M. Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 0.5 mL, 0.67 mL and 4.02 mL Capacity. Report Number KOA-201302 May 16, 2013 (Child 12-068, 13-018; Adult 12-069, 13-018).
Volume 2	US 16 CFR § 1700	Tillman, A. M. Overview of Child Resistant Packaging Studies: Thermoforme Blister Pack for Pipettes of 0.5 mL, 0.67 mL and 4.02 mL Capacity. Report Number KOA-201303. June 11, 2013
Volume 3	US 16 CFR § 1700	Novosad, M. Child Resistant Packaging Test Summary Report: Thermoforme Blister Pack for Pipettes of 0.5 mL, 0.67 mL and 4.02 mL Capacity. Report Number KOA-201301. May 16, 2013 (Child 12-068, 13-018; Adult 12-069, 13-018).

Tru Prodigy believes this application falls under Category R340 (54: Amendment requiring data review within RD). The fee due which has been paid is \$3,607 with a PRIA decision time line of 4 months.

We trust you will find this application complete. However, please feel free to contact me by email at Ann@PyxisRC.com or by phone ((253) 853-7369) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Tru Prodigy c/o Pyxis Regulatory Consulting, 4110 136th St NW, Gig Harbor WA 98332 (253)853-7369	EPA Registration Number/File Symbol 88966-1
Active Ingredient(s) and/or representative test compound(s) Fipronil	Date 7/19/13
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Residential Indoor	Product Name VetGuard for Cats

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 7/19/13	Typed or Printed Name and Title Ann M. Tillman, Agent
---------------	-----------------	--

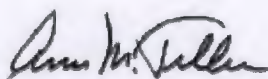
Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

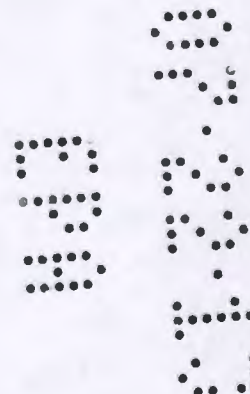
PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
088966-1	July 19, 2013	088966-1.20130719.VetGuard for Cats Label.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.



Signature
Ann M. Tillman
Agent for Tru Prodigy

July 19, 2013
Date



**Child Resistant Packaging Certification
For Tru Prodigy's VetGuard for Cats
(EPA Registration No. 88966-1)**

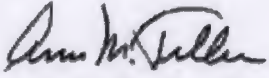
Registrant: Tru Prodigy
500 E. Shore Drive, Suite 130
Eagle, ID 83616

I certify that the packaging that will be used for this product meets the standards of 40 CFR 157.32.

EPA Registration No. 88966-1, VetGuard for Cats is **filled and packaged by Firma Klocke Verpackungs-Service GmbH**. The package consists of a placebo filled pipette with a clear plastic front and foil backing that is contained in a blister. The blister has a clear plastic front (PET/PP/PE transp. LDPE – 350/100/75) and a foil backing (PET/AL/PET/PE – 12/12/12/75). Three blisters are connected to each other. The blister is the child-resistant packaging. The pipette has one fill level, which is 0.017 fl. oz. (0.5 mL). Child Resistant Packaging, CRP, testing was conducted on the blister with a placebo filled pipette at 0.5 mL (**MRID 48755301, 48703054**) – NCRT Child study no. 10-028 and NCRT Senior study no. 11-043).

EPA Registration No. 88966-1, VetGuard for Cats may also be **filled and packaged by Klocke of America, Inc.** The package consists of a placebo filled pipette with a clear plastic front and foil backing that is contained in a blister. The blister has a clear plastic front (PET/PP/PE transp. LDPE – 350/100/75) and a foil backing (PET/AL/PET/PE – 12/12/12/75). Three blisters are connected to each other. The blister is the child-resistant packaging. The pipette has one fill level, which is 0.017 fl. oz. (0.5 mL). Child Resistant Packaging, CRP, testing was conducted on the blister with a placebo filled pipette at 0.5 mL (**MRID pending**) – NCRT Child study no. 12-068). These data support previous Child Resistant Packaging, CRP, testing that was conducted on the blister with a placebo filled pipette at 0.5 mL (**MRID 48755301**) – NCRT Child study no. 10-028 and NCRT Senior study no. 11-043).

I realize that additional CRP testing may be required if EPA Registration No. 88966-1, VetGuard for Cats is **not filled and packaged by Firma Klocke Verpackungs-Service GmbH or Klocke of America, Inc. on the same equipment as the samples tested** (0.5 mL) - **MRID 48755301** – NCRT Child study no. 10-028 and NCRT Senior study nos. 11-043) and – **MRID pending**, NCRT Child study no. 12-068. Further, any change in CRP opening instructions from those used in testing, color, size, and/or materials for the CRP may result in additional CRP testing for EPA Registration No. 88966-1, VetGuard for Cats.



Ann M. Tillman
Agent for Tru Prodigy
Pyxis Regulatory Consulting, Inc.

July 19, 2013
Date

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

CONTAINS CONFIDENTIAL BUSINESS INFORMATION – REDACTED VERSION

July 19, 2013

OVERNIGHT DELIVERY

Richard Gebken (PM 10)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Tru Prodigy
VetGuard for Cats (EPA File Symbol 88966-1)
Application to Amend Pesticide Registration
PRIA Category R340 (Primary Application)

Dear Mr. Gebken,

On behalf of Tru Prodigy, we are submitting an application to amend the registration of VetGuard for Cats to add an additional manufacturing site. This application is tied to the secondary application to amend the registration of VetGuard for Dogs (EPA Reg. No. 88966-2).

This amendment would allow packaging to be done at Klocke of America (KOA) in Fort Myers, FL in addition to the current location in Germany. KOA conducted limited child resistant package testing with CRP made at the Florida as agreed upon at a meeting between KOA and EPA in November 2012. The new data are submitted with this amendment.

Minor product label changes were made to reflect the location of the new manufacturer and to include the VetIQ logo, per previous discussions between EPA and Tru Prodigy.

In support of this application, we submit the following documents:

1. Application for an Amended Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4) dated July 19, 2013

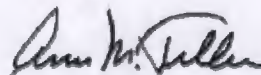
3. One (1) copy of the revised label with changes tracked
4. Three (3) copies of the revised label with changes accepted
5. A CD containing an electronic version of the labels
6. Certification with Respect to Label Integrity
7. Agency Internal Use Copy of the Data Matrix
8. Public File Copy of the Data Matrix
9. Certification with Respect to Citation of Data (EPA Form 8570-34)
10. Child Resistant Packaging Certification
11. Copy of the PRIA payment from pay.gov
12. Copy of this letter with CBI redacted
13. Copy of the cover letter for VetGuard for Dogs, the secondary application
14. Letter of authorization from sponsor of CRP testing
15. Letter of Authorization from Tru Prodigy
16. Product Specific Data (3 copies each):

Volume 1	US 16 CFR § 1700	Novosad, M. Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 0.5 mL, 0.67 mL and 4.02 mL Capacity. Report Number KOA-201302. May 16, 2013 (Child 12-068, 13-018; Adult 12-069, 13-018).
Volume 2	US 16 CFR § 1700	Tillman, A. M. Overview of Child Resistant Packaging Studies: Thermoforme Blister Pack for Pipettes of 0.5 mL, 0.67 mL and 4.02 mL Capacity. Report Number KOA-201303. June 11, 2013
Volume 3	US 16 CFR § 1700	Novosad, M. Child Resistant Packaging Test Summary Report: Thermoforme Blister Pack for Pipettes of 0.5 mL, 0.67 mL and 4.02 mL Capacity. Report Number KOA-201301. May 16, 2013 (Child 12-068, 13-018; Adult 12-069, 13-018).

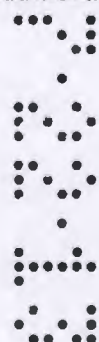
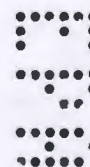
Tru Prodigy believes this application falls under Category R340 (54: Amendment requiring data review within RD). The fee due which has been paid is \$3,607 with a PRIA decision time line of 4 months.

We trust you will find this application complete. However, please feel free to contact me by email at Ann@PyxisRC.com or by phone ((253) 853-7369) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman



Enclosures

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

July 19, 2013

OVERNIGHT DELIVERY

Richard Gebken (PM 10)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

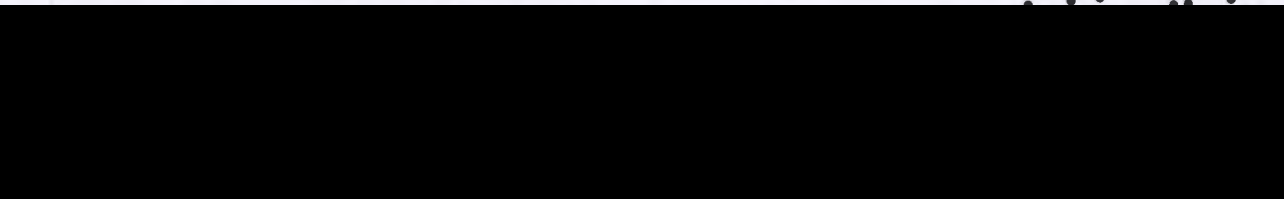
RE: Tru Prodigy
VetGuard for Dogs (EPA File Symbol 88966-2)
Application to Amend Pesticide Registration
PRIA Category R340 (Secondary Application)

Dear Mr. Gebken,

On behalf of Tru Prodigy, we are submitting an application to amend the registration of VetGuard for Dogs to add an additional manufacturing site. This application is tied to the primary application to amend the registration of VetGuard for Cats (EPA Reg. No. 88966-1).

This amendment would allow packaging to be done at Klocke of America (KOA) in Fort Myers, FL in addition to the current location in Germany. KOA conducted limited child resistant package testing with CRP made at the Florida as agreed upon at a meeting between KOA and EPA in November 2012. The new data are submitted with this amendment.

Minor product label changes were made to reflect the location of the new manufacturer and to include the VetIQ logo, per previous discussions between EPA and Tru Prodigy.



In support of this application, we submit the following documents:

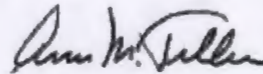
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12. Copy of this letter with CBI redacted
13. Copy of the cover letter for VetGuard for Cats, the primary application
14. Letter of authorization from sponsor of CRP testing
15. Letter of Authorization from Tru Prodigy

Tru Prodigy believes this application falls under Category R340. Since the data to support this amendment is being submitted with the primary application, Tru Prodigy requests that EPA authorize a discretionary refund of 75% of the PRIA fee of \$3617. Therefore, Tru Prodigy has paid a fee of \$904 for this action.

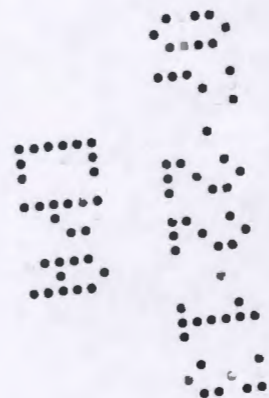
We trust you will find this application complete. However, please feel free to contact me by email at Ann@PyxisRC.com or by phone ((253) 853-7369) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures





KLOCKE OF AMERICA, INC.
INNOVATIVE PACKAGING SOLUTIONS

July 17, 2013

Richard Gebken (PM 10)
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Subject: Letter of Authorization

Dear Mr. Gebken:

Please let this letter serve to notify you that Tru Prodigy (EPA Company Number 88966) is authorized to submit and rely upon the following Child Resistant Packaging (CRP) data in support of its registrations of VetGuard for Dogs (EPA Reg. No. 88966-2) and VetGuard for Cats (EPA Reg. No. 88966-1) pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIRA), 7 USC Section 136 et seq.:

Citation	MRID Number
Novosad, M. Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 0.5 mL, 0.67 mL and 4.02 mL Capacity. Report Number KOA-201302. May 16, 2013 (Child 12-068, 13-018; Adult 12-069, 13-018).	
Tillman, A. M. Overview of Child Resistant Packaging Studies: Thermoforme Blister Pack for Pipettes of 0.5 mL, 0.67 mL and 4.02 mL Capacity. Report Number KOA-201303. June 11, 2013	
Novosad, M. Child Resistant Packaging Test Summary Report: Thermoforme Blister Pack for Pipettes of 0.5 mL, 0.67 mL and 4.02 mL Capacity. Report Number KOA-201301. May 16, 2013 (Child 12-068, 13-018; Adult 12-069, 13-018).

Klocke of America, Inc. owns the above listed data and submission by Tru Prodigy does not confer ownership rights of these data. Other companies may rely on these data without compensation to Tru Prodigy.

Sincerely,
7/17/13
Donald W. Hopta, VP & General Manager
Klocke of America, Inc.
1420 Jetport Loop, Fort Myers, FL 33913
Phone: 239-561-5800, x237
Fax: 239-561-5811
Cell: 609-209-0223

14201 Jetport Loop, Fort Myers, FL 33913-7713
phone 239.561.5800 fax 239.561.5811

website www.klockeamerica.com email packaging@klockeamerica.com



**TRU
PRODIGY**

500 E. Shore Dr. Suite 120 Eagle, Idaho 83616 Ph: (208) 939-8900 Fax: 208-939-3200

January 3, 2012

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Ann Tillman, Mike Kellogg, Leanne Pruett, Ross Gilbert, Janelle Kay, Maryanne Geisbush or Arianna Shorey of Pyxis Regulatory Consulting, Inc. is authorized to act as agent for Tru Prodigy, LLC (EPA Company Number [pending]), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

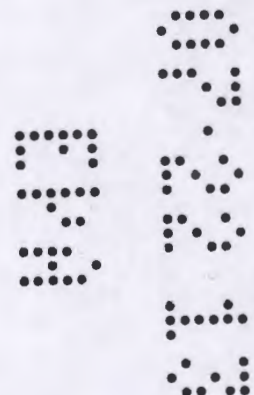
If you have any questions, please do not hesitate to contact me at 208-939-8900 x311.

Sincerely,

Cord Christensen

CEO

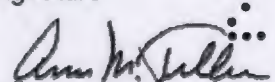
cc: Pyxis Regulatory Consulting, Inc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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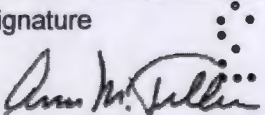
DATA MATRIX

Date July 19, 2013			EPA Reg. No./File Symbol 88966-		Page 1 of 7
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748			Product VetGuard for Cats		
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	48755401	Tru Prodigy	OWN	
830.1600	Description of Materials Used to Produce the Product	48755401	Tru Prodigy	OWN	
830.1620	Description of Production Process				Not required ¹
830.1650	Description of Formulation Process	48755401	Tru Prodigy	OWN	
830.1670	Discussion of Formation of Impurities	48755401	Tru Prodigy	OWN	
830.1700	Preliminary Analysis				Not Required ²
830.1750	Certified Limits	48755401	Tru Prodigy	OWN	
830.1800	Enforcement Analytical Method	48755401	Tru Prodigy	OWN	
830.6302	Color	48755402	Tru Prodigy	OWN	
830.6303	Physical State	48755402	Tru Prodigy	OWN	
830.6304	Odor	48755402	Tru Prodigy	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions				Not Required ³
830.6314	Oxidation Reduction: Chemical Incompatibility	48755402	Tru Prodigy	OWN	
830.6315	Flammability	48755402	Tru Prodigy	OWN	
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 19, 2013

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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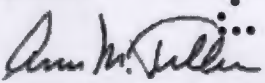
DATA MATRIX

Date July 19, 2013			EPA Reg. No./File Symbol 88966-		Page 2 of 7
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748			Product VetGuard for Cats		
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6316	Explodability	48755403	Tru Prodigy	OWN	Waiver ⁴
830.6317	Storage Stability	49109201	Tru Prodigy	OWN	
830.6319	Miscibility				Not required ⁵
830.6320	Corrosion Characteristics	49109201	Tru Prodigy	OWN	
830.6321	Dielectric Breakdown Voltage				Not required ⁶
830.7000	pH	48755402	Tru Prodigy	OWN	
830.7050	UV/Visible Absorption				
830.7100	Viscosity	48755402	Tru Prodigy	OWN	
830.7200	Melting Point/Melting Range				Not required ⁷
830.7220	Boiling Point/Boiling Range				Not required ⁸
830.7300	Density/Relative Density/Bulk Density	48755402	Tru Prodigy	OWN	
830.7370	Dissociation Constants in Water				Not required ⁸
830.7520	Particle size, fiber length, diameter distribution	48755403	Tru Prodigy	OWN	Waiver ⁸
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Not required ⁸
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 19, 2013

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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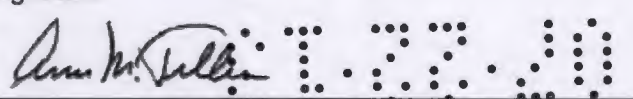
DATA MATRIX

Date July 19, 2013			EPA Reg. No./File Symbol 88966-		Page 3 of 7
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748			Product VetGuard for Cats		
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550
830.7840	Water Solubility: Column Elution Method; Shake Flask Method				Not required ^B
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure				Not required ^B
870.1100	Acute Oral Toxicity: Rat	43577705 43951703		OLD OLD	
870.1200	Acute Dermal Toxicity: Rat	43577706		OLD	
870.1300	Acute Inhalation Toxicity: Rat	43577707		OLD	
870.2400	Primary Eye Irritation: Rabbit	43577708		OLD	
870.2500	Primary Dermal Irritation	43577709		OLD	
870.2600	Dermal Sensitization	43577710		OLD	
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 19, 2013

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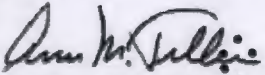
DATA MATRIX

Date July 19, 2013			EPA Reg. No./File Symbol 88966-		Page 4 of 7
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748			Product VetGuard for Cats		
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7200	Companion Animal Safety	Cite-all		PAY	
810.3300	Product Performance	Cite-all		PAY	
US 16 CFR § 1700	Child Resistant Packaging Study	48755301 48703054	Tru Prodigy Chanelle Pharmaceuticals Manufacturing Ltd.	PER PER	
Fipronil Generic and Product Specific Data Requirements					
Tru Prodigy will make offers-to-pay to the following companies on the fipronil data submitters list of April 8, 2013.					
		Cite-All	Syngenta Crop Protection LLC	PAY	
		Cite-All	The Scotts Company	PAY	
		Cite-All	Bayer Cropscience LP	PAY	
		Cite-All	Bayer Environmental Science	PAY	
		Cite-All	Whitmire Micro-Gen Research Laboratories	PAY	
		Cite-All	Pfizer, Inc.	PAY	
		Cite-All	Virbac AH, Inc.	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 19, 2013
		Cite-All	Sergeant's Pet Care Products, Inc.	PAY	

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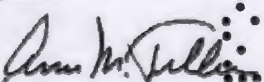
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Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	The Hartz Mountain Corp.	PAY	
		Cite-All	Reckitt Benckiser LLC	PAY	
		Cite-All	Cheminova A/S	PAY	
		Cite-All	J. J. Mauget Co.	PAY	
		Cite-All	BASF Corp.	PAY	
		Cite-All	Chemsico	PAY	
		Cite-All	Makhteshim Chemical Works Ltd.	PAY	
		Cite-All	Gharda Chemicals Limited	PAY	
		Cite-All	Control Solutions Inc.	PAY	
		Cite-All	Virbac	PAY	
		Cite-All	Combat Insect Control Systems	PAY	
		Cite-All	Pyrethroid Working Group	PAY	
		Cite-All	Merial Limited	PAY	
		Cite-All	Spray Drift Task Force	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 19, 2013
		Cite-All	Cheminova Inc.	PAY	

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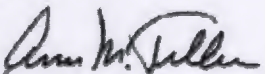

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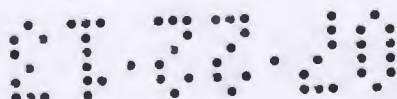
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Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Outdoor Residential Exposure Task Force	PAY	
		Cite-All	Agricultural Reentry Task Force	PAY	
		Cite-All	Ambrands	PAY	
		Cite-All	Innovative Pest Control Products	PAY	
		Cite-All	FIFRA Endangered Species Task Force	PAY	
		Cite-All	Irvita Plant Protection N.V.	PAY	
		Cite-All	Residential Exposure Joint Venture	PAY	
		Cite-All	Agricultural Handlers Exposure Task Force	PAY	
		Cite-All	Ceva Animal Health, LLC	PAY	
		Cite-All	Sharda USA LLC	PAY	
		Cite-All	Gharda Generics, Inc.	PAY	
		Cite-All	Fidopharm, Inc.	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 19, 2013
		Cite-All	Norbrook Laboratories, Ltd.	PAY	

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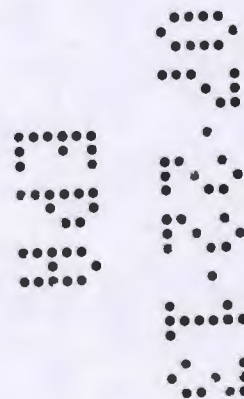
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Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748		Product VetGuard for Cats			
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Loradochem, Inc.	PAY	
		Cite-All	Linouvel, Inc.	PAY	
		Cite-All	Zhejiang Hisun Pharmaceuticals Co., Ltd.	PAY	
		Cite-All	Argite - Fipronil LLC	PAY	
		Cite-All	Firponex Solutions Inc.	PAY	
		Cite-All	Virbac S. A.	PAY	
		Cite-All	Raymat Materials Inc.	PAY	
		Cite-All	Chanelle Pharmaceuticals Manufacturing	PAY	
		Cite-All	Horizon Valley Generics, Inc.	PAY	
		Cite-All	American Vet Sciences, LLC	PAY	
Signature  			Name and Title Ann M. Tillman, Consultant		Date July 19, 2013



Endnotes for Data Matrix for VetGuard for Cats

- ¹ **830.1620** – These data are not required for the registration of an end-use product. See 830.1650 for formulation process information.
- ² **830.1700** – This product does not consist solely of the technical grade active ingredient (TGA) and is not produced by an integrated system, therefore, per OPPTS 830.1700, these data are not required.
- ³ **830.6313** – These data are not required for registration of an end-use product.
- ⁴ **830.6316** - Tru Prodigy requested a waiver from this data requirement because fipronil does not have the chemical bonds or functional groups associated with explosive chemicals. There are no potentially explosive ingredients in VetGuard for Cats (refer to the CSF for VetGuard for Cats). EPA accepted this waiver in a review dated July 17, 2012 (DP Barcode 401382).
- ⁵ **830.6319** - This data requirement is required when the product is an emulsifiable liquid and to be diluted with petroleum solvents. VetGuard for Cats is not an emulsifiable concentrate and its labeling does not allow it to be diluted with petroleum solvents; therefore this data requirement is not applicable to VetGuard.
- ⁶ **830.6321** - These data are required if the product is an end-use product and is applied around electrical equipment. VetGuard is not to be applied around electrical equipment; therefore this data requirement is not applicable.
- ⁷ **830.7200, 830.7220, 830.7370, 830.7550-7570, 830.7840-7860, 830.7950** – These data are not required for registration of an end-use product.
- ⁸ **830.7520** – Tru Prodigy requested a waiver for this data requirement for VetGuard because the product is not a fibrous material and is not a water-insoluble material. EPA did not require this study as a condition of registration (see EPA review dated July 17, 2012; DP Barcode 401382).

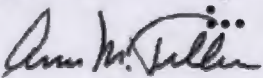


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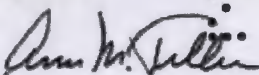
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Applicant's/Registrant's Name & Address Tru Prodigy 500 E. Shore Drive, Suite 130 Eagle, ID 83616		Product VetGuard for Cats			
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Tru Prodigy	OWN	
			Tru Prodigy	OWN	
					Not required ¹
			Tru Prodigy	OWN	
			Tru Prodigy	OWN	
					Not Required ²
			Tru Prodigy	OWN	
			Tru Prodigy	OWN	
			Tru Prodigy	OWN	
			Tru Prodigy	OWN	
			Tru Prodigy	OWN	
					Not Required ³
			Tru Prodigy	OWN	
			Tru Prodigy	OWN	
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 19, 2013

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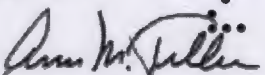
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Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Tru Prodigy	OWN	Waiver ⁴
			Tru Prodigy	OWN	
					Not required ⁵
			Tru Prodigy	OWN	
					Not required ⁶
			Tru Prodigy	OWN	
			Tru Prodigy	OWN	
					Not required ⁷
					Not required ⁸
			Tru Prodigy	OWN	
					Not required ⁸
			Tru Prodigy	OWN	Waiver ⁸
					Not required ⁸
					See 830.7550
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 19, 2013

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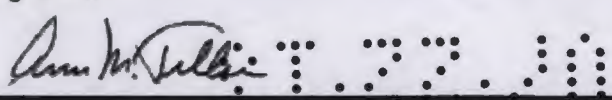
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Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					See 830.7550
					Not required ^B
					See 830.7840
					Not required ^B
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 19, 2013

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Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				PAY	
				PAY	
			Tru Prodigy	PER	
			Tru Prodigy	PER	
			Tru Prodigy	PER	
			Chanelle Pharmaceuticals	PER	
			Manufacturing Ltd.		
			Signature 		
			Pfizer, Inc.	PAY	
			Virbac AH, Inc.	PAY	

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Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Sergeant's Pet Care Products, Inc.	PAY	
			The Hartz Mountain Corp.	PAY	
			Reckitt Benckiser LLC	PAY	
			Cheminova A/S	PAY	
			J. J. Mauget Co.	PAY	
			BASF Corp.	PAY	
			Chemsico	PAY	
			Makhteshim Chemical Works Ltd.	PAY	
			Gharda Chemicals Limited	PAY	
			Control Solutions Inc.	PAY	
			Virbac	PAY	
			Combat Insect Control Systems	PAY	
			Pyrethroid Working Group	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 19, 2013
			Merial Limited	PAY	
			Spray Drift Task Force	PAY	

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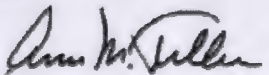
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Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Cheminova Inc.	PAY	
			Outdoor Residential Exposure Task Force	PAY	
			Agricultural Reentry Task Force	PAY	
			Ambrands	PAY	
			Innovative Pest Control Products	PAY	
			FIFRA Endangered Species Task Force	PAY	
			Irvida Plant Protection N.V.	PAY	
			Residential Exposure Joint Venture	PAY	
			Agricultural Handlers Exposure Task Force	PAY	
			Ceva Animal Health, LLC	PAY	
			Sharda USA LLC	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 19, 2013
			Gharda Generics, Inc.	PAY	
			Fidopharm, Inc.	PAY	

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Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Norbrook Laboratories, Ltd.	PAY	
			Loradochem, Inc.	PAY	
			Linouvel, Inc.	PAY	
			Zhejiang Hisun Pharmaceuticals Co., Ltd.	PAY	
			Argite – Fipronil LLC	PAY	
			Firponex Solutions Inc.	PAY	
			Virbac S. A.	PAY	
			Raymat Materials Inc.	PAY	
			Chanelle Pharmaceuticals Manufacturing	PAY	
			Horizon Valley Generics, Inc.	PAY	
			American Vet Sciences, LLC	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 19, 2013

There is an **ELECTRONIC LABEL** for this action

You can use Acrobat to compare the e-label to the previous version (and find the changes). You can also use Acrobat to mark-up the e-label with your comments.

If e-label was submitted via

CD-ROM with paper application

then you will find e-label in

Electronic Label Library

If the e-label is not found in the ELL then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the Front End.

or

If e-label was submitted via

XML E-Submission (no paper)

then you will find e-label in

Documentum

See overview of processing e-labels on other side of this sheet.

If you have any questions on e-labels, please contact one of your division e-label experts:

AD	Willie Abney	308-1689
	Renae Whitaker	308-7003
	Tracy Lantz	308-6415
BPPD		
RD	Tom Harris	308-9423

1. Package Insert
2. Carton (front, back, inside and side panels)
3. [Optional text for front or Optional text for back of cardboard insert if security packaging used]
4. Optional card with tips for use
5. Reminder Stickers
6. Text for back of blister
7. Text for back of pipette (applicator)

Note to reviewer: optional text is placed in brackets

1. Package Insert, Text

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil:9.7%

INERT INGREDIENTS:90.3%

TOTAL:100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

[Waterproof]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Effective treatment that kills adult fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*), and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, and anaplasmosis]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills adult mosquitoes]

Package Insert, Text

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IF SWALLOWED: Immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Have the product container label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-888-314-8588 for emergency medical treatment information.

HAZARDS TO DOMESTIC ANIMALS

For external use only on cats. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

Side Effects. After applying VetGuard for Cats, check your cat for side-effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea have been reported from grooming after treatment. If you observe these signs or symptoms in your treated cat, contact your veterinarian. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON DOGS OR OTHER ANIMALS.

VetGuard for Cats is approved for use on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks.

VetGuard for Cats keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

Package Insert, Text

Frequency of Application

Monthly application of VetGuard for Cats controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days.

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

Ticks: VetGuard for Cats kills ticks for at least one month. Apply VetGuard for Cats every 30 days to control ticks (larva, nymph and adult) that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis.

Chewing Lice: VetGuard for Cats kills chewing lice for at least one month. Apply VetGuard for Cats every 30 days to control chewing lice.

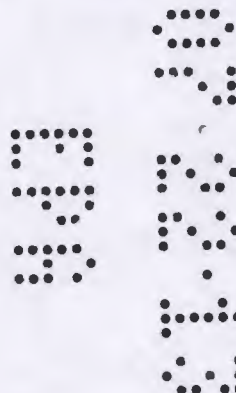
Mosquitoes: Apply VetGuard for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Use VetGuard for Cats on all cats including breeding, pregnant and lactating queens, and on kittens 8 weeks or older.

A one-spot application is convenient and easy for effective treatment of fleas, ticks, chewing lice, and mosquitoes. Apply VetGuard for Cats when your cat is dry.

VetGuard for Cat is applied at a single point on the surface of the skin between the cat's shoulders and rapidly covers the entire cat by localizing in the hair, on the surface of the skin and in the sebaceous glands.

Soon after coming into contact with a treated cat, fleas, ticks, mosquitoes, and chewing lice are killed. To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:



Package Insert, Text

Remove and Open Package

- 1** Cut along scissor cut line to separate unit



- 2** Turn unit over and cut corner at bulb end



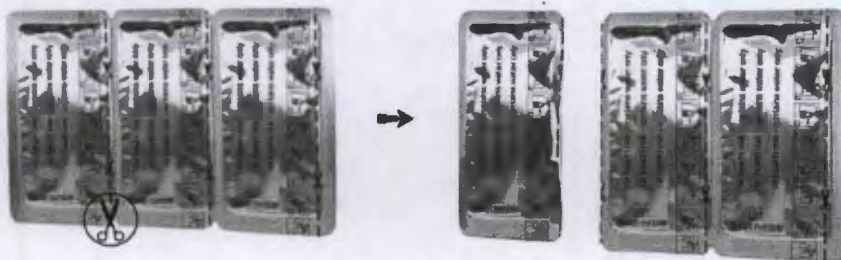
- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



- 1** Cut along scissor cut line to separate unit



- 2** Turn unit over and cut corner at bulb end



- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



Package Insert, Text

Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open.

Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.



PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store unused product in original container only, out of reach of children and animals.

CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of Tru Prodigy. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Tru Prodigy makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither Tru Prodigy, the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages

Package Insert, Text

resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

EPA Reg. No.: 88966-1

[EPA Est. No. :]

Manufactured for:

Tru Prodigy
500 E. Shore Drive, Suite 130
Eagle, ID 83616

[Customer Service: 1-888-314-8588]

[For more information, visit www.vetguard.com, www.vetguardplus.com, www.vetguardpro.com]

[Made in Germany]

[Product of USA]

[Made in the US]

[VetGuard for Cats is a registered trade name of Tru Prodigy]

[Optional Bar Code]

2. Carton Text – Front Panel

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil:.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:100.0%

Net Contents [3-pak] 0.051 fl. oz. (1.5 mL) (3 tubes containing 0.017 fl. oz. each)

[3 Doses]

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for First Aid and Precautionary Statements.

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

[Waterproof]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Effective treatment that kills fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, and anaplasmosis]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills adult mosquitoes]

[Kills fleas, ticks, chewing lice and mosquitoes]

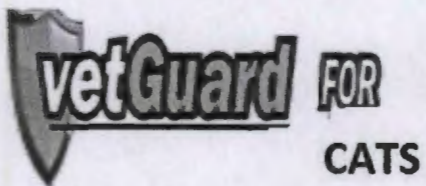
[3 Month Supply]

[3 Applicators]

FREE APP AT

www.VETGUARDPLUS.com

VETIQ



2. Carton Text – Back Panel

VETGUARD FOR CATS

[3 Doses]

[Quick-acting]

[Long-lasting]

[Waterproof]

[3 Month Supply]

FREE APP AT

www.VETGUARDPLUS.com

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE.

Manufactured for:

Tru Prodigy
500 E. Shore Drive, Suite 130
Eagle, ID 83616

[Customer Service: 1-888-314-8588]

EPA Reg. No. 88966-1

EPA Est. No.

[Made in Germany]

[Made in the US]

[For more information, visit www.vetguard.com, www.vetguardplus.com, www.vetguardpro.com]]

[Batch/Lot No.]

[Bar Code]

[VetGuard for Cats is a registered trade name of Tru Prodigy]

VetGuard for Cats can be used on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks. VetGuard for Cats controls fleas, ticks, chewing lice and mosquitoes and keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

DIRECTIONS FOR USE

It is a violation of law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR CAT, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON DOGS OR ON OTHER ANIMALS.**

Side Effects. See package insert for side effects.

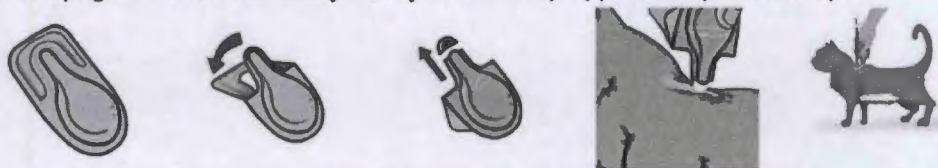
To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:

Remove and Open Package

See package insert for opening instructions.

Open Applicator and Apply VetGuard for Cats

Hold upright with foil side away from you and snap applicator tip back to open.



Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.

VETIQ

2. Carton Text - Inside Panel

[3 Month Supply]

READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE.

USE ONLY ON CATS & KITTENS 8 WEEKS AND OLDER

KEEP OUT OF REACH OF CHILDREN

CAUTION

VetGuard for Cats can be used on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks. VetGuard for Cats controls fleas, ticks, chewing lice and mosquitoes and keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

Frequency of Application

Monthly application of VetGuard for Cats controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days.

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

Ticks: VetGuard for Cats kills ticks for at least one month. Apply VetGuard for Cats every 30 days to control ticks (larva, nymph and adult) that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis.

Chewing Lice: VetGuard for Cats kills chewing lice for at least one month. Apply VetGuard for Cats every 30 days to control chewing lice.

Adult Mosquitoes: Apply VetGuard for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store unused product in original container only, out of reach of children and animals.

CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

2. Carton Text –Side Panel

VETIQ

VetGuard for catsCats

[3 Month Supply]

[EPA Reg. No. 88966-1]

[EPA Est. No.]

[Batch/Lot No.]

[Made in the US]

3. [Optional text for front of cardboard insert if security packaging used]

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil:.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:.....100.0%

Net Contents (one box) [0.051 fl. oz. (1.5 mL), 3 tubes containing 0.017 fl. oz. each, 3 doses]

Net Contents (two boxes) [1.02 fl. oz. (3.0 mL), each box has 3 tubes containing 0.017 fl. oz. each, 6 doses]

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for First Aid and Precautionary Statements.

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

[Waterproof]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Effective treatment that kills fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, and anaplasmosis]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills adult mosquitoes]

[Kills fleas, ticks, chewing lice and mosquitoes]

[3 Month Supply]

[3 Applicators]

FREE APP AT

[www.VETGUARDPLUS.com]

EPA Reg. No. 88966-1

EPA Est. No.

Manufactured for:

Tru Prodigy

500 E. Shore Drive, Suite 130

Eagle, ID 83616

[Customer Service: 1-888-314-8588]

[Made in the US]

[Bar code]

[For more information, visit www.vetguard.com, www.vetguardplus.com, www.vetguardpro.com]

VETIQ

vetGuard FOR
CATS



3. [Optional text for back of cardboard insert if security packaging used]

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil:.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:.....100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[Quick-acting]

[Long-lasting]

[Waterproof]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Effective treatment that kills adult fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, and anaplasmosis]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills adult mosquitoes]

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IF SWALLOWED: Immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Have the product container label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-888-314-8588 for emergency medical treatment information.

HAZARDS TO DOMESTIC ANIMALS

For external use only on cats. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using **ANY** pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

Side Effects. After applying VetGuard for Cats, check your cat for side-effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea have been reported from grooming after treatment. If you observe these signs or symptoms in your treated cat, contact your veterinarian. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR PET, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON DOGS OR OTHER ANIMALS.**

VetGuard for Cats is approved for use on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks.

VetGuard for Cats keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

Frequency of Application

Monthly application of VetGuard for Cats controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days.

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

Ticks: VetGuard for Cats kills ticks for at least one month. Apply VetGuard for Cats every 30 days to control ticks (larva, nymph and adult) that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis.

Chewing Lice: VetGuard for Cats kills chewing lice for at least one month. Apply VetGuard for Cats every 30 days to control chewing lice.

Mosquitoes: Apply VetGuard for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Use VetGuard for Cats on all cats including breeding, pregnant and lactating queens, and on kittens 8 weeks or older.

A one-spot application is convenient and easy for effective treatment of fleas, ticks, chewing lice, and mosquitoes. Apply VetGuard for Cats when your cat is dry.

VetGuard for Cat is applied at a single point on the surface of the skin between the cat's shoulders and rapidly covers the entire cat by localizing in the hair, on the surface of the skin and in the sebaceous glands.

Soon after coming into contact with a treated cat, fleas, ticks, mosquitoes, and chewing lice are killed. To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:

Remove and Open Package

- 1** Cut along scissor cut line to separate unit



- 2** Turn unit over and cut corner at bulb end



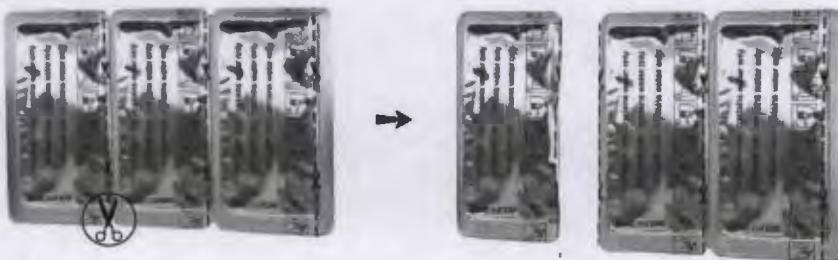
- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



- 1** Cut along scissor cut line to separate unit



- 2** Turn unit over and cut corner at bulb end



- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open.

Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.



PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store unused product in original container only, out of reach of children and animals.

CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of Tru Prodigy. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Tru Prodigy makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither Tru Prodigy, the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

VETIQ

4. [Optional Card with Tips, Text]

[Optional marketing claims]

[VetGuard for Cats]

[See other side for stickers to remind you it's time to reapply VetGuard for Cats.]

[Some Tips and Other Information for Using VetGuard for Cats]

[Treat dogs and cats separately and only with the proper dose of VetGuard for Dogs or VetGuard for Cats.]

[Follow the label instructions for how to apply and be sure that VetGuard for Cats is applied to the skin, not on top of the fur and not near the collar. Removing the collar before application may help to prevent the collar from absorbing the VetGuard dose.]

[Apply VetGuard for Cats when your cat is dry. Make sure you apply all of the dose that is in the applicator.]

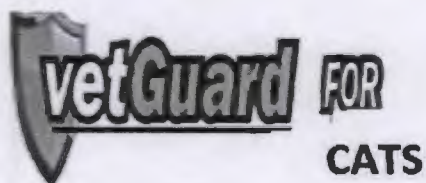
[Even indoor cats need flea and tick control if other household pets bring fleas into the home.]

[Fleas have many life stages and serious infestations can take up to 3 applications every 30 days for control. In fact, the flea life-cycle in the home can last as long as 21 days.]

The logo for VETIQ, featuring the word "VETIQ" in a bold, sans-serif font. The letters are white and set against a dark, rounded rectangular background. A thin vertical line is positioned to the left of the logo.

5. Text for Reminder Stickers

VETIQ



[Reminder: It's time to repurchase VetGuard for Cats!]

Use these stickers to remind you when to apply and to purchase VetGuard for Cats.

The first time you treat your cat, peel off the sticker and place on your calendar that day. To remind you when the next application is due, place the other two stickers on your calendar 1 and 2 months after the first application.

[For Customer Service call 1-888-314-8588.]

[For more information, visit www.vetguard.com, www.vetguardplus.com, www.vetguardpro.com]]

[For more information, visit www.xxxx.com]



[Optional Bar code]

6. Text for Back of Blister

Pictogram of Back of Blister With Opening Instructions



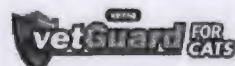
6. Text for Back of Blister



ONLY FOR CATS AND KITTENS
9.7% FIPRONIL
0.017 fl. oz (0.5 mL)
EPA Reg. No. 88966-1

KEEP OUT OF REACH OF CHILDREN

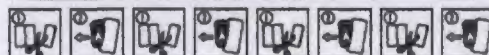
CAUTION: see full label for additional instructions
and precautions before using



ONLY FOR CATS AND KITTENS
9.7% FIPRONIL
0.017 fl. oz (0.5 mL)
EPA Reg. No. 88966-1

KEEP OUT OF REACH OF CHILDREN

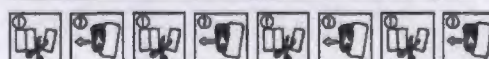
CAUTION: see full label for additional instructions
and precautions before using



ONLY FOR CATS AND KITTENS
9.7% FIPRONIL
0.017 fl. oz (0.5 mL)
EPA Reg. No. 88966-1

KEEP OUT OF REACH OF CHILDREN

CAUTION: see full label for additional instructions
and precautions before using



KEEP OUT OF REACH OF CHILDREN

CAUTION: See full label for additional instructions and precautions before using

Only for Cats & Kittens

VetGuard for Cats

EPA Reg. No. 88966-1

Lot/Batch No.

0.017 fl. oz. (0.5 mL)

9.7% Fipronil

7. Text for back of pipette (applicator)

KEEP OUT OF REACH OF CHILDREN

CAUTION: See full label for additional instructions and precautions before using

Only for Cats & Kittens

VETIQ™

VetGuard for Cats

EPA Reg. No. 88966-1

Lot/Batch No.

0.017 fl. oz. (0.5 mL)

9.7% Fipronil

SENDER: COMPLETE THIS SECTION

- Complete Items 1, 2, and 3. Also complete Item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Ms. Ann M. Tillman, Ph.D.
 Plyxis Reg. Consulting, Inc.
 4110 136th Street NW
 Gig Harbor, WA 98332

2. Article Number
(Transfer from service label)

7008 3230 0000 9482 3517

PS Form 3811, February 2004

Domestic Return Receipt

102595-02-M-1540

COMPLETE THIS SECTION ON DELIVERY

Signature

X *[Signature]*

☐ Agent☐ Addressee

B. Received by (Printed Name)

[Signature]

C. Date of Delivery

2-19

D. Is delivery address different from Item 1?

☐ Yes

If YES, enter delivery address below:

☐ No

3. Service Type

☒ Certified Mail☐ Express Mail☐ Registered☐ Return Receipt for Merchandise☐ Insured Mail☐ C.O.D.

4. Restricted Delivery? (Extra Fee)

☐ Yes

UNITED STATES POSTAL SERVICE



• S

FCL 10025936

address, and ZIP+4 in this box •

Mr. Carmen Rodia (7504P)
 U.S. Environmental Prot. Agency
 1200 Pennsylvania Ave., NW
 Washington, DC 20460

(EPA Reg. No. 88966-1 PM-10)

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City, State, ZIP+4

PS Form 3811, February 2004

See Back for Instructions



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Wednesday, April 9, 2013

CERTIFIED MAIL: (Article Number 7008 3230 0000 9482 3555)

Ms. Ann M. Tillman, Ph.D.
Regulatory Agent for Tru Prodigy
c/o Plyxis Regulatory Consulting, Inc.
4110 136th Street NW
Gig Harbor, WA 98332-9122

**Subject: Confirmation of Receipt; Tru Prodigy's Response to EPA Letters Dated February 12, 2013
EPA Reg. Nos. 88966-1 (VETGUARD FOR CATS) & 88966-2 (VETGUARD FOR DOGS)
Your Response Dated March 21, 2013**

Dear Ms. Tillman:

This purpose of this correspondence is to acknowledge that the Agency has received a response to its letters dated February 12, 2013, via Tru Prodigy's attorney (Paley & Rothman), dated March 21, 2013. Please note that the Agency is not going to pursue any regulatory action related to Tru Prodigy's use of the trade name "VetGuard" on the referenced products at this time. However, we will be reevaluating our current policy as it applies to the "VetGuard" trade name, and will keep Tru Prodigy informed of our findings.

If you have any questions about this letter, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov or Mr. Richard J. Gebken at (703) 305-6701 or via e-mail at Gebken.Richard@epa.gov during the hours of 9:00 A.M. to 5:30 P.M. EST.

Sincerely yours,

Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

088966-00001 D475055
088966-00002 D475057

Decision Seq: 475055

Action Code: 360 ACTION INITIATED BY THE AGENCY, 110

Decision Status

FFS Start Date:

Tentative Ind: No

Start/Stop Clock

FQPA Clock:

Due Date: 02-Jun-2013

75-Day Due Date:

Days Elapsed:

OPP Target Due Date:

21-Day Due Date:

FFS Original Decision:

Negotiated Due Date:

45/90 Due Date:

Registrant

Predecisional

Response Due Date:

Due Date:

Current Status: PENDING (12-Feb-2013)

Tracking

Create Resubmission

FFS Letters

Waiver Documentation

Action Code History

Secondary Decision

75 Day Letters

45/90 Day Screen

Primary Decisions

FFS Negotiated Due Dates

12 OPP Target Due Date

Decision Comments

Payment

Unmatched Payments

Decision Ownership

Receipts

Data Package

Reduced Risk

Meetings & Milestones

FFS Information

Receipts

Staff Member

Reg/DCI Number

Submission Due Dt

Response

S: 930995

Rodia, Carmen

88966-1

02-Jun-2013

PENDING

Removal of VetGuard as a tradename



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Tuesday, February 12, 2013

CERTIFIED MAIL: (Article Number 7008 3230 0000 9482 3517)

Ms. Ann M. Tillman, Ph.D.
Regulatory Agent for Tru Prodigy
c/o Plyxis Regulatory Consulting, Inc.
4110 136th Street NW
Gig Harbor, WA 98332-9122

Subject: Recent Audit of Regulatory File
EPA Registration No.: 88966-1
Product Name: VETGUARD FOR CATS

Dear Ms. Tillman:

The Agency has received a number of inquiries/complaints regarding your client's (Tru Prodigy) use of the trade name "VetGuard" on the label of its VETGUARD FOR CATS (EPA Reg. No. 88966-1) product, which was registered on September 20, 2012. These complaints have stated that the use of the trade name "VetGuard" is false and misleading to the consumer since the product is not restricted to retail sale from only veterinarians; therefore, the Agency has rescinded your client's use of the trade name "VetGuard."

In order to correct the above mentioned problem, within 45 days of the date of this letter (that is, by or before Friday, March 29, 2013), you must submit, on behalf of your client, a revised master label as an amendment noting a trade name change from "VetGuard" to another trade name that is acceptable to the Agency. If we do not receive a revised master label, the Agency may pursue further regulatory action, including cancellation under section 6 of FIFRA.

If you have any questions about this letter, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov or Mr. Richard J. Gebken at (703) 305-6701 or via e-mail at Gebken.Richard@epa.gov during the hours of 9:00 A.M. to 5:30 P.M. EST.

Sincerely yours,

Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

088966-00001 D475055

Material Sent for Data Extraction

Reg. # 88966-1

Description: Accepted MFA - PEN 93/10.

☒ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated _____

☒ Notification Dated 1/10/2013

☒ New CSF(s) Dated 1/8/2013 - revised Basil

☐ Other: _____

☒ Decision #: 474282

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Alganesh Debesai

Phone: 308-8353 Division: RD

Date: 2/3/13



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 31, 2013

Ms. Ann M. Tillman
Agent for Tru Prodigy
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332

Subject: Minor Formulation Amendment
VetGuard for Cats
EPA Reg. No. 88966-1

Dear Ms. Tillman:

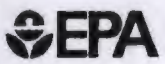
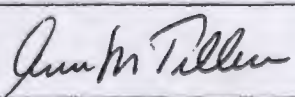
The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 1/10/2013 for **EPA Registration 88966-1**. The Registration Division (RD) has conducted a review of the Confidential Statement of Formulae (CSF) submitted with this request for its applicability under PRN 98-10 and finds that the change(s) requested fall within the scope of PRN 98-10. Therefore, the **revised Basic Formulation CSF dated 1/8/2013 is acceptable**. A copy of the CSF has been added to the registration file for the subject product. As per your request, the amended CSF will replace all previously approved CSFs on file.

If you have any questions, please contact me via telephone at 703-308-8353 or e-mail (debesai.alganesesh@epa.gov).

Sincerely,

Alganesesh Debesai

Alganesesh Debesai
Inert Ingredient Assessment Branch (IIAB)
Registration Division (7505P)
Office of Pesticide Programs

 United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number Tru Prodigy/88966-1		2. EPA Product Manager R. Gebken	
4. Company/Product (Name) Tru Prodigy/VetGuard for Cats		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Tru Prodigy c/o Pyxis Regulatory Consulting 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
Section - II			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.) Notification of a new source of active ingredient and alternate suppliers of inert ingredients per PRN 98-10, submission of Basic Formulation. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.			
Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. 0.017 oz. No. per container 3	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt _____ No. per container _____	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 0.051 fl. oz.	
5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product		6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other on box and on insert in box	
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Ann M. Tillman		Title Agent	Telephone No. (Include Area Code) (253) 853-7309
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment, both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent	
4. Typed Name Ann M. Tillman		5. Date 1/10/13	

D# 474282
PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

MFA
Dec 2/2013
Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

January 10, 2013

COURIER DELIVERY

Richard Gebken (PM 10)
Document Processing Desk (**NOTIF**)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Tru Prodigy
VetGuard for Cats (EPA Reg. No. 88966-1)
Notification per PRN 98-10 for New Source of Active Ingredient

Dear Mr. Gebken,

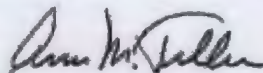
On behalf of Tru Prodigy, we are submitting a notification to replace the source of active ingredient in VetGuard for Cats (EPA Reg. No. 88966-1). The new source is a registered product and is registered for the same uses for which the formulated product is registered and is similar to the current source. In addition to replacing the source of active ingredient, other non-notification changes include a new address for Tru Prodigy and addition of alternate suppliers for the inert ingredients. Please note that the CSF for VetGuard for Cats has been revised per EPA's new policy for listing alternate suppliers of inert ingredients and therefore the current CSFs (Basic and Alternate #1) dated 5/17/2012 are being **replaced** with the enclosed Basic CSF dated January 8, 2013.

In support of this notification, we submit the following documents:

1. Application for Pesticide Registration (EPA Form 8570-1)
2. Two (2) copies of the VetGuard for Cats Basic CSF dated January 8, 2013
3. Formulator's Exemption, EPA Form 8570-27
4. Copies of the MSDSes and Certificates of Analysis from each of the five new suppliers of the inert ingredients
5. Letter of Authorization

We trust you will find this submission is complete. However, please feel free to contact me by email at Ann@PyxisRC.com or by phone (253-853-7369) if you have any questions ~~or need~~ any additional information.

Sincerely,



Ann M. Tillman

Enclosures



500 E. Shore Dr. Suite 120 Eagle, Idaho 83616 Ph: (208) 939-8900 Fax: 208-939-3200

January 3, 2012

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Ann Tillman, Mike Kellogg, Leanne Pruett, Ross Gilbert, Janelle Kay, Maryanne Geisbush or Arianna Shorey of Pyxis Regulatory Consulting, Inc. is authorized to act as agent for Tru Prodigy, LLC (EPA Company Number [pending]), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

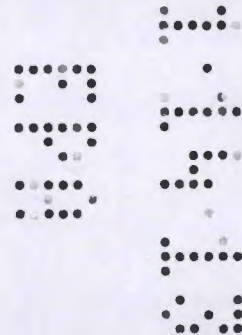
If you have any questions, please do not hesitate to contact me at 208-939-8900 x311.

Sincerely,

Cord Christensen

CEO

cc: Pyxis Regulatory Consulting, Inc.





United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Tru Prodigy 500 E. Shore Drive, Suite 130 Eagle, ID 83616	EPA File Symbol/Registration Number 88966-1 ✓
	Product Name VetGuard for Cats ✓
	Date of Confidential Statement of Formula (EPA Form 8570-4) 01/08/2013 ✓ letter dated 1.10.13.

As an authorized representative of the applicant for registration of the product identified above, I certify that:

- (1) This product contains the following active ingredient(s):

fipronil

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

- (3) Indicate by checking (A) or (B) below which paragraph applies:

- ☐ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

- ☒ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

- (4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Fipronil ✓	[REDACTED]	[REDACTED]
Signature <i>Ann M. Tillman</i>	Name and Title Ann M. Tillman, Agent	Date 1/10/13

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 29, 2013

Ms. Ann M. Tillman
Tru Prodigy c/o Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332

Subject: Application for Pesticide Amendment
VetGuard for Cats
EPA Reg. No. 88966-1
Your Submission Dated October 3, 2012
Decision No: 474189

Dear Ms. Tillman:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the conditions of registration and label comments below. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

Conditions of acceptance

1. This registration is now time-limited and expires two years from the date of this letter.
2. Please consider limiting the formulations of this product to one basic confidential statement of formula. The Agency may require this in the future and no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning April 1, 2013.

Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kaitlon Keller).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number

Product name (brand name)

Lot #

Where purchased: internet, store, veterinarian

Active Ingredient(s)

Weight range for product

Date on which incident occurred. (mm/dd/yyyy)

State in which the incident occurred. (standard 2 letter abbreviation)

Registrant case #

Species: dog, cat, other (specify)

Breed: (as reported by pet owner)

Age: months or years

Sex: M, F, or neutered

Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other

Body System: neurological, dermatological, GI, respiratory, ocular, other

Major signs noted with separate column for each sign, using standard terminology

Time to Onset: (hours, days)

Treated by veterinarian: yes or no

First time product used: yes or no

Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)

Any known precondition

EPA Severity Code: death, major, moderate, minor

Outcome: died, recovered, still treated, unknown

4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- All incidents should be reported including all minor dermal and ocular irritation reports.
- Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.

- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.

Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all spot-on products, the Agency will inform registrants and if needed, EPA may take regulatory action. If you have any questions contact Driss Benmhend at 703-308-9525 or by e-mail at: Benmhend.driss@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10,
Insecticide Branch
Registration Division (7505P)

Enclosure: *Label stamped "Accepted"*

1. Package Insert
2. Carton (front, back, inside and side panels)
3. [Optional text for front or Optional text for back of cardboard insert if security packaging used]
4. Optional card with tips for use
5. Reminder Stickers
6. Text for back of blister
7. Text for back of pipette (applicator)

Note to reviewer: optional text is placed in brackets

1. Package Insert, Text

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil:9.7%

INERT INGREDIENTS:90.3%

TOTAL:100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

[Waterproof]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Effective treatment that kills adult fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, and anaplasmosis]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills adult mosquitoes]

ACCEPTED
with COMMENTS
In EPA Letter Dated
JAN 29 2013

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.

88966-1

Package Insert, Text

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IF SWALLOWED: Immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Have the product container label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-888-314-8588 for emergency medical treatment information.

HAZARDS TO DOMESTIC ANIMALS

For external use only on cats. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using **ANY** pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. You may also contact **SAFETYCALL INTERNATIONAL** at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

Side Effects. After applying VetGuard for Cats, check your cat for side-effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea have been reported from grooming after treatment. If you observe these signs or symptoms in your treated cat, contact your veterinarian. You may also contact **SAFETYCALL INTERNATIONAL** at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR PET, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.**

VetGuard for Cats is approved for use on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks.

VetGuard for Cats keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

Package Insert, Text

Frequency of Application

Monthly application of VetGuard for Cats controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days.

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

Ticks: VetGuard for Cats kills ticks for at least one month. Apply VetGuard for Cats every 30 days to control ticks (larva, nymph and adult) that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis.

Chewing Lice: VetGuard for Cats kills chewing lice for at least one month. Apply VetGuard for Cats every 30 days to control chewing lice.

Mosquitoes: Apply VetGuard for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Use VetGuard for Cats on all cats including breeding, pregnant and lactating queens, and on kittens 8 weeks or older.

A one-spot application is convenient and easy for effective treatment of fleas, ticks, chewing lice, and mosquitoes. Apply VetGuard for Cats when your cat is dry.

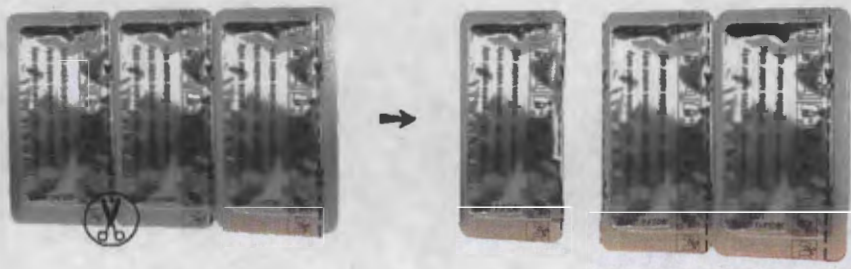
VetGuard for Cat is applied at a single point on the surface of the skin between the cat's shoulders and rapidly covers the entire cat by localizing in the hair, on the surface of the skin and in the sebaceous glands.

Soon after coming into contact with a treated cat, fleas, ticks, mosquitoes, and chewing lice are killed. To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:

Package Insert, Text

Remove and Open Package

- 1** Cut along scissor cut line to separate unit



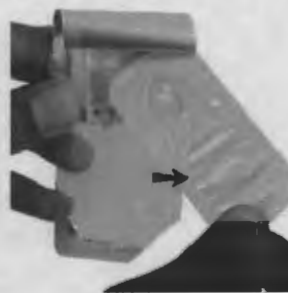
- 2** Turn unit over and cut corner at bulb end



- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



Package Insert, Text

Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open.

Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.



PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store unused product in original container only, out of reach of children and animals.

CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of Tru Prodigy. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Tru Prodigy makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither Tru Prodigy, the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages

Package Insert, Text

resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

EPA Reg. No.: 88966-1

[EPA Est. No.]

Manufactured for:

Tru Prodigy
500 E. Shore Drive, Suite 130
Eagle, ID 83616

[Made in Germany]

[VetGuard for Cats is a registered trade name of Tru Prodigy]

[Optional Bar Code]

2. Carton Text – Front Panel

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil:.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:.....100.0%

Net Contents [3-pak] 0.051 fl. oz. (1.5 mL) (3 tubes containing 0.017 fl. oz. each)

[3 Doses]

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for First Aid and Precautionary Statements.

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

[Waterproof]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Effective treatment that kills fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, and anaplasmosis]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

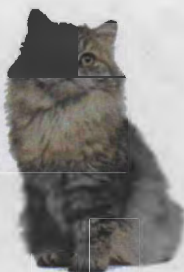
[Kills adult mosquitoes]

[Kills fleas, ticks, chewing lice and mosquitoes]

[3 Month Supply]

[3 Applicators]

[FREE APP AT www.VETGUARDPLUS.com]



2. Carton Text – Back Panel

VETGUARD FOR CATS

[Quick-acting]

[Long-lasting]

[Waterproof]

[3 Month Supply]

[FREE APP AT www.VETGUARDPLUS.com]

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE.

Manufactured for:

Tru Prodigy
500 E. Shore Drive, Suite 130
Eagle, ID 83616

EPA Reg. No. 88966-1

EPA Est. No.

[Made in Germany]

[Batch/Lot No.]

[Bar Code]

[VetGuard for Cats is a registered trade name of Tru Prodigy]

VetGuard for Cats can be used on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks. VetGuard for Cats controls fleas, ticks, chewing lice and mosquitoes and keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

DIRECTIONS FOR USE

It is a violation of law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR CAT, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS OR ON OTHER ANIMALS.**

Side Effects. See package insert for side effects.

To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:

Remove and Open Package

See package insert for opening instructions.

Open Applicator and Apply VetGuard for Cats

Hold upright with foil side away from you and snap applicator tip back to open.



Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.

2. Carton Text - Inside Panel

[3 Month Supply]

READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE.

USE ONLY ON CATS & KITTENS 8 WEEKS AND OLDER

KEEP OUT OF REACH OF CHILDREN

CAUTION

VetGuard for Cats can be used on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks. VetGuard for Cats controls fleas, ticks, chewing lice and mosquitoes and keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

Frequency of Application

Monthly application of VetGuard for Cats controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days.

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

Ticks: VetGuard for Cats kills ticks for at least one month. Apply VetGuard for Cats every 30 days to control ticks (larva, nymph and adult) that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis.

Chewing Lice: VetGuard for Cats kills chewing lice for at least one month. Apply VetGuard for Cats every 30 days to control chewing lice.

Adult Mosquitoes: Apply VetGuard for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store unused product in original container only, out of reach of children and animals.

CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

2. Carton Text –Side Panel

VetGuard for cats

[3 Month Supply]

[EPA Reg. No. 88966-1]

[EPA Est. No.]

3. [Optional text for front of cardboard insert if security packaging used]

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:.....100.0%

Net Contents (one box) [0.051 fl. oz. (1.5 mL), 3 tubes containing 0.017 fl. oz. each, 3 doses]

Net Contents (two boxes) [1.02 fl. oz. (3.0 mL), each box has 3 tubes containing 0.017 fl. oz. each, 6 doses]

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for First Aid and Precautionary Statements.

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

[Waterproof]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Effective treatment that kills fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, and anaplasmosis]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills adult mosquitoes]

[Kills fleas, ticks, chewing lice and mosquitoes]

[3 Month Supply]

[3 Applicators]

[FREE APP AT www.VETGUARDPLUS.com]

EPA Reg. No. 88966-1

EPA Est. No.

Manufactured for:

Tru Prodigy

500 E. Shore Drive, Suite 130

Eagle, ID 83616

[Bar code]



3. [Optional text for for back of cardboard insert if security packaging used]

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil:.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[Quick-acting]

[Long-lasting]

[Waterproof]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Effective treatment that kills adult fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, and anaplasmosis]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills adult mosquitoes]

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IF SWALLOWED: Immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Have the product container label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-888-314-8588 for emergency medical treatment information.

HAZARDS TO DOMESTIC ANIMALS

For external use only on cats. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using **ANY** pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

Side Effects. After applying VetGuard for Cats, check your cat for side-effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea have been reported from grooming after treatment. If you observe these signs or symptoms in your treated cat, contact your veterinarian. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR PET, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.**

VetGuard for Cats is approved for use on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks.

VetGuard for Cats keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

Frequency of Application

Monthly application of VetGuard for Cats controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days.

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

Ticks: VetGuard for Cats kills ticks for at least one month. Apply VetGuard for Cats every 30 days to control ticks (larva, nymph and adult) that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis.

Chewing Lice: VetGuard for Cats kills chewing lice for at least one month. Apply VetGuard for Cats every 30 days to control chewing lice.

Mosquitoes: Apply VetGuard for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Use VetGuard for Cats on all cats including breeding, pregnant and lactating queens, and on kittens 8 weeks or older.

A one-spot application is convenient and easy for effective treatment of fleas, ticks, chewing lice, and mosquitoes. Apply VetGuard for Cats when your cat is dry.

VetGuard for Cat is applied at a single point on the surface of the skin between the cat's shoulders and rapidly covers the entire cat by localizing in the hair, on the surface of the skin and in the sebaceous glands.

Soon after coming into contact with a treated cat, fleas, ticks, mosquitoes, and chewing lice are killed. To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:

Remove and Open Package

- 1** Cut along scissor cut line to separate unit



- 2** Turn unit over and cut corner at bulb end



- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open.

Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.



PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store unused product in original container only, out of reach of children and animals.

CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of Tru Prodigy. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Tru Prodigy makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither Tru Prodigy, the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

4. [Optional Card with Tips, Text]

[Optional marketing claims]

[VetGuard for Cats]

[See other side for stickers to remind you it's time to reapply VetGuard for Cats.]

[Some Tips and Other Information for Using VetGuard for Cats]

[Treat dogs and cats separately and only with the proper dose of VetGuard for Dogs or VetGuard for Cats.]

[Follow the label instructions for how to apply and be sure that VetGuard for Cats is applied to the skin, not on top of the fur and not near the collar. Removing the collar before application may help to prevent the collar from absorbing the VetGuard dose.]

[Apply VetGuard for Cats when your cat is dry. Make sure you apply all of the dose that is in the applicator.]

[Even indoor cats need flea and tick control if other household pets bring fleas into the home.]

[Fleas have many life stages and serious infestations can take up to 3 applications every 30 days for control. In fact, the flea life-cycle in the home can last as long as 21 days.]

5. Text for Reminder Stickers



[Reminder: It's time to repurchase VetGuard for Cats!]

Use these stickers to remind you when to apply and to purchase VetGuard for Cats.

The first time you treat your cat, peel off the sticker and place on your calendar that day. To remind you when the next application is due, place the other two stickers on your calendar 1 and 2 months after the first application.

[For Customer Service call 1-888-314-8588.]

[For more information, visit www.xxxxx.com]



[Optional Bar code]

Pictogram of Back of Blister With Opening Instructions



6. Text for Back of Blister

KEEP OUT OF REACH OF CHILDREN

CAUTION: See full label for additional instructions and precautions before using

Only for Cats & Kittens

VetGuard for Cats

EPA Reg. No. 88966-1

Lot/Batch No.

0.017 fl. oz. (0.5 mL)

9.7% Fipronil

7. Text for back of pipette (applicator)

KEEP OUT OF REACH OF CHILDREN

CAUTION: See full label for additional instructions and precautions before using

Only for Cats & Kittens

VetGuard for Cats

EPA Reg. No. 88966-1

Lot/Batch No.

0.017 fl. oz. (0.5 mL)

9.7% Fipronil

Decision Information for 88966-1

Decision Seq: 474189 Action Code: 300, LABEL REVISION; NO DATA REQUIRED; 90

FFS Start Date: Tentative Ind: Start/Stop Clock FQPA Clock:

Due Date: 05-Feb-2013 75-Day Due Date: Days Elapsed:

OPP Target Due Date: 21-Day Due Date: FFS Original Decision:

Negotiated Due Date: 45/90 Due Date:

Registrant: Predecisional Due Date:

Response Due Date:

Current Status: PENDING (22-Jan-2013)

75 Day Letters 45/90 Day Screen Primary Decisions

FFS Negotiated Due Dates 12 OPP Target Due Date Decision Comments Payment Unmatched Payments

Decision Ownership Receipts Data Package Reduced Risk Meetings & Milestones FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 929592	Benmhend, Driss	88966-1	05-Feb-2013	PENDING

NA

Received by P.B 1/23/13

Viewing Record 1 of 1

Get the last approved label & check -

OK



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Tru Prodigy/88966-1	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Tru Prodigy/VetGuard for Cats	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Tru Prodigy c/o Pyxis Regulatory Consulting 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label amendment to clarify directions for use on packaging

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.017 oz.	No. per container 3	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 0.051 fl. oz.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input checked="" type="checkbox"/> Other on box and on insert in box		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Ann M. Tillman	Title Agent	Telephone No. (Include Area Code) (253) 853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Ann M. Tillman	5. Date 10/31/2012	

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

October 31, 2012

DELIVERY BY EMAIL

Richard Gebken (PM 10)
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Tru Prodigy
VetGuard for Cats (EPA File Symbol 88966-1)
Application for Amendment

Dear Mr. Gebken,

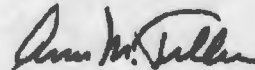
On behalf of Tru Prodigy, we are submitting an application to amend the label for VetGuard for Cats (EPA Reg. No. 88966-1). Most of the changes are minor in nature to accommodate printing of final packaging and to include text that was inadvertently omitted on the label submitted with the original application for registration. Tru Prodigy is anxious to have this amendment approved so that they can meet their production of packaging schedule which is planned for November.

In support of this amendment, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. One (1) copy of the revised label with changes tracked
3. One (1) copy of the label with changes accepted
4. Letter of Authorization

We trust you will find this amendment is complete. However, please feel free to contact me by email at Ann@PyxisRC.com or by phone ((253) 853-7369) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures

Decision Information for 8966-1

Decision Seq: 472685
Action Code: 100,NO DATA REQUIRED,,0

Decision Status

Tracking

Create Resubmission

FFS Letters

Waiver Documentation

Action Code History

Secondary Decision

FFS Start Date
Tentative Ind: No
Start/Stop Clock
FQPA Clock:

Due Date 31-Oct-2012
75-Day Due Date:
Days Elapsed:

OPP Target Due Dt:
21-Day Due Date:
FFS Original Decision:

Negotiated Due Dt:
45/90 Due Date:

Registrant:
Response Due Date:

Current Status: PENDING (06-Dec-2012)

75 Day Letters
45/90 Day Screen
Primary Decisions

FFS Negotiated Due Dates
12 OPP Target Due Date
Decision Comments
Payment
Unmatched Payments

Decision Ownership
Receipts
Data Package
Reduced Risk
Meetings & Milestones
FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 327712	Rodla, Carmen	88966-1	31-Oct-2012	PENDING

Projected Product Release date 2/13/2013.

Viewing Record 1 of 1

Carmen.
 Place in file. closed out 12/6/2012



October 19, 2012

Mr. Richard Gebken (PM 10)
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Tru Prodigy
VetGuard for Cats (EPA Reg. No. 88966-1)
Projected Product Release Date Per Conditions of Registration

Dear Mr. Gebken:

I am writing to inform you that Tru Prodigy is planning a product release date of February 15, 2013 for EPA Reg. No.. 88966-1. Thank you for your help with this matter.

Sincerely,

Scott Stewart
Vice President of Product Development



Material Sent for Data Extraction

Reg. # 88966-1

Description: _____

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 9-20-12

☐ Notification Dated _____

☒ New CSF(s) Dated 2-24-12

☐ Other: _____

☒ Decision #: 461924

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Carmen Rodia

Phone: (703) 306-0327 Division: RD/IB

Date: 9-20-12

**ENVIRONMENTAL PROTECTION AGENCY**

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Registration No.

88966-1

Date of Issuance:

September 20, 2012**NOTICE OF PESTICIDE:**

- ☒ Registration
☐ Reregistration

(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

VETGUARD FOR CATS**Name and Address of Registrant (include ZIP Code):**

Tru Prodigy
c/o Plyxis Regulatory Consulting, Inc.
4110 136th Street NW
Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This action is taken under the authority of section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.

Terms of Registration

1. EPA has registered the product listed above provided that the following change is made to the label before you release the product for shipment:
 - a. Revise the EPA Registration Number to read: "EPA Registration No 88966-1."
2. This registration is **time-limited and expires two years from the date this product is first released for shipment**. You must provide the Agency with a projected "release for shipment date", in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected "release for shipment date" until an actual release for shipment date is provided in writing.
3. Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e., no alternate formulations or minor formulation amendments will be submitted and/or approved for this product, except to allow for alternate sources of any individual inert ingredient).

Signature of Approving Official:

Refer to Page 3

Richard J. Gebken, Product Manager (10)
Registration Division, Insecticide Branch

Date:

September 20, 2012

4. You must submit the following data within the timeframe described below:
Within sixteen (16) months of the date on this Notice of Registration, provide to the Agency acceptable data packages for Guideline Studies: OPPTS 830.6320 (Corrosion Characteristics) and OPPTS 830.6317 (Storage Stability).
5. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on August 1, 2012. The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information (CBI) as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kimberly Nesci).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
Product name (brand name)
Lot#
Where purchased: internet, store, Veterinarian
Active Ingredient(s)
Weight range for product
Date on which incident occurred, (mm/dd/yyyy)
State in which the incident occurred, (standard 2 letter abbreviation)
Registrant case #
Species: dog, cat, other (specify)
Breed: (as reported by pet owner)
Age: months or years
Sex: M, F, or neutered
Weight: pounds
Primary Route of Exposure: dermal, oral, other animal, inhalation, other
Body System: neurological, dermatological, GI, respiratory, ocular, other Major signs noted
Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no
Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
Any known precondition
EPA Severity Code: death, major, moderate, minor
Outcome: died, recovered, still treated, unknown

6. Along with the enhanced incident reporting, you must submit an analysis of all incidents seen, to include the following details:
 - a. All minor dermal and ocular irritation reports.
 - b. Summary table for cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - c. A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - d. Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
 - e. A summary table for s showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
 - f. A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label.
 - g. A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range.
 - h. Table showing number of incidents for each cat breed.
 - i. Table showing number of incidents in cat for each clinical sign.

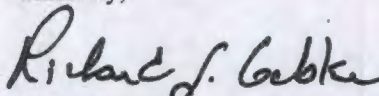
- j. Table showing number of incidents in cat for each organ system.
- k. Report aggregate incidents, but do not combine moderate and minor incidents.
- 7. If EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform all registrants concerned. If mitigation measures are necessary, EPA may take regulatory action.
- 8. Tru Prodigy must adequately address all of the mitigation actions identified in the Agency's *Generic Pet Spot-On Mitigation Plan* available at the following internet site: <http://www.epa.gov/pesticides/health/spot-on-meetings.html>.

You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for registration review of your product under FIFRA.

Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If you fail to comply with all of the **Terms of Registration** stated above, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e) and/or automatically expire. Your release for shipment of the product constitutes your acceptance of these conditions.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. If you have any questions concerning this action, please contact Mr. Richard J. Gebken at (703) 305-6701 or gebken.richard@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7505C)

Enclosure

[Note to reviewer: optional text is placed in brackets]

[Package Insert, Text]

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil:.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:.....100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

[Waterproof]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Effective treatment that kills adult fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, and anaplasmosis]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills adult mosquitoes]

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

ACCEPTED
With COMMENTS
In EPA Letter Dated:
September 20, 2012
Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:
88966-1

[Package Insert, Text]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store unused product in original container only, out of reach of children and animals.

CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IF SWALLOWED: Immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Have the product container label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-888-314-8588 for emergency medical treatment information.

HAZARDS TO DOMESTIC ANIMALS

For external use only on cats. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using **ANY** pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

Side Effects. After applying VetGuard for Cats, check your cat for side-effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea have been reported from grooming after treatment. If you observe these signs or symptoms in your treated cat, contact your veterinarian. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent

[Package Insert, Text]

veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame.

VetGuard for Cats is approved for use on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks.

VetGuard for Cats keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

Frequency of Application

Monthly application of VetGuard for Cats controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days.

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

Ticks: VetGuard for Cats kills ticks for at least one month. Apply VetGuard for Cats every 30 days to control ticks (larva, nymph and adult) that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis.

Chewing Lice: VetGuard for Cats kills chewing lice for at least one month. Apply VetGuard for Cats every 30 days to control chewing lice.

Mosquitoes: Apply VetGuard for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Use VetGuard for Cats on all cats including breeding, pregnant and lactating queens, and on kittens 8 weeks or older.

A one-spot application is convenient and easy for effective treatment of fleas, ticks, chewing lice, and mosquitoes. Apply VetGuard for Cats when your cat is dry.

VetGuard for Cat is applied at a single point on the surface of the skin between the cat's shoulders and rapidly covers the entire cat by localizing in the hair, on the surface of the skin and in the sebaceous glands.

Soon after coming into contact with a treated cat, fleas, ticks, mosquitoes, and chewing lice are killed. To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:

[Package Insert, Text]

Remove and Open Package

- 1** Cut along scissor cut line to separate unit



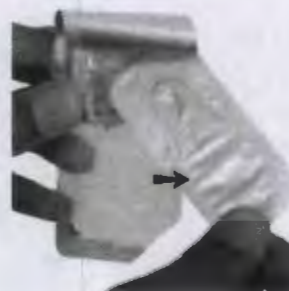
- 2** Turn unit over and cut corner at bulb end



- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open.

Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.



LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

[Package Insert, Text]

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of Tru Prodigy. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Tru Prodigy makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither Tru Prodigy, the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

EPA Reg. No.: 88966-R

EPA Est. No.:

Manufactured for:

Tru Prodigy
500 E. Shore Drive, Suite 130
Eagle, ID 83616

[Made in Germany]

[VetGuard for Cats is a registered trade name of Tru Prodigy]

[Optional Bar Code]

[Carton Text - Front]

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:.....100.0%

Net Contents 0.21 fl. oz. (1.5 mL [3 tubes containing 0.017 fl. oz. each])

3 Doses

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for First Aid and Precautionary Statements.

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

[Waterproof]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Effective treatment that kills fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

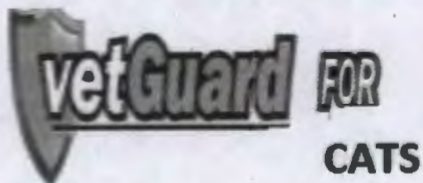
[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, and anaplasmosis]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills adult mosquitoes]

[Kills fleas, ticks, chewing lice and mosquitoes]





Manufactured for:

Tru Prodigy
500 E. Shore Drive, Suite 130
Eagle, ID 83616

[VetGuard for Cats is a registered trade name of Tru Prodigy]

EPA Reg. No. 88966-R

EPA Est. No.

[Made in Germany]

[Carton Text - Back]

VETGUARD FOR CATS

VetGuard for Cats can be used on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks. VetGuard for Cats controls fleas, ticks, chewing lice and mosquitoes and keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

DIRECTIONS FOR USE

It is a violation of law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR CAT, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS OR ON OTHER ANIMALS.**

Side Effects. See package insert for side effects.

To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:

Remove and Open Package

See package insert for opening instructions.

Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open.

Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.



[Carton Text - Back]

Frequency of Application

Monthly application of VetGuard for Cats controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days.

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

Ticks: VetGuard for Cats kills ticks for at least one month. Apply VetGuard for Cats every 30 days to control ticks (larva, nymph and adult) that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis.

Chewing Lice: VetGuard for Cats kills chewing lice for at least one month. Apply VetGuard for Cats every 30 days to control chewing lice.

Adult Mosquitoes: Apply VetGuard for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Manufactured for:
Tru Prodigy
500 E. Shore Drive, Suite 130
Eagle, ID 83616

EPA Reg. No. 88966-R

EPA Est. No.

[Made in Germany]

[VetGuard for Cats is a registered trade name of Tru Prodigy]

[Carton Text – Front, Back, or Side Panel]

EPA Reg. No. 88966-R

EPA Est. No.

Batch/Lot No.

[Made in Germany]

[Insert with Tips, Front Side, Text]

[Optional marketing claims]

VetGuard for Cats

See other side for stickers to remind you it's time to reapply VetGuard for Cats.

Some Tips and Other Information for Using VetGuard for Cats

Treat dogs and cats separately and only with the proper dose of VetGuard for Dogs or VetGuard for Cats.

Follow the label instructions for how to apply and be sure that VetGuard for Cats is applied to the skin, not on top of the fur and not near the collar. Removing the collar before application may help to prevent the collar from absorbing the VetGuard dose.

Apply VetGuard for Cats when your cat is dry. Make sure you apply all of the dose that is in the applicator.

Even indoor cats need flea and tick control if other household pets bring fleas into the home.

Fleas have many life stages and serious infestations can take up to 3 applications every 30 days for control. In fact, the flea life-cycle in the home can last as long as 21 days.

[Insert with Tips, Back Side, Text with Stickers]

Calendar Reminder Stickers

Reminder: It's time to repurchase VetGuard for Cats!

You can use these stickers to remind you when to apply and to purchase VetGuard for Cats.

The first time you treat your cat, peel off the sticker and place on your calendar that day. To remind you when the next application is due, place the other two stickers on your calendar 1 and 2 months after the first application.

3 Months

Sticker 1: Apply VetGuard for Cats

Sticker 2: Apply VetGuard for Cats

Sticker 3: Apply VetGuard for Cats

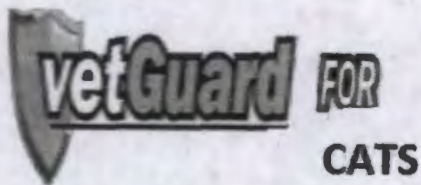
For Customer Service call 1-888-314-8588.

[For more information, visit www.xxxxx.com]

Tru Prodigy

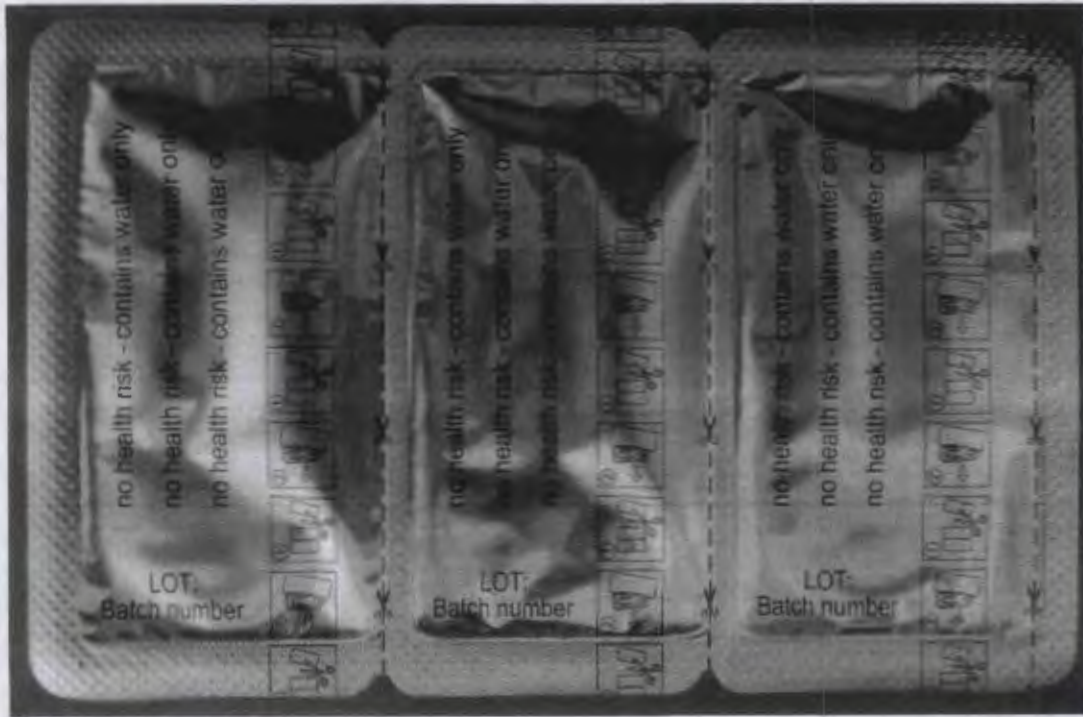
Tru Prodigy

500 E. Shore Drive, Suite 130
Eagle, ID 83616



[Optional Bar code]

[Pictogram of Back of Blister With Opening Instructions]



[Text for Back of Blister]

KEEP OUT OF REACH OF CHILDREN

CAUTION: See full label for additional instructions and precautions before using

Only for Cats & Kittens

VetGuard for Cats

EPA Reg. No. 88966-R

Lot/Batch No.

0.017 fl. oz. (0.5 mL)

9.7% Fipronil



Copies of NORs for the Tru Prodigy New Product Registrations

Carmen Rodia to: Ann Tillman

09/20/2012 02:54 PM

Cc: Richard Gebken

Bcc: Carmen Rodia

From: Carmen Rodia/DC/USEPA/US
To: Ann Tillman <Ann@PyxisRC.com>
Cc: Richard Gebken/DC/USEPA/US@EPA
Bcc: Carmen Rodia/DC/USEPA/US

Ann, attached are e-copies of the NORs for the referenced Tru Prodigy new product registrations.
Regards, Carmen Rodia.



88966-1 (VETGUARD FOR CATS), Unconditional Registration (09-20-12).pdf



88966-2 (VETGUARD FOR DOGS), Unconditional Registration (09-20-12).pdf

Carmen J. Rodia, Jr.
Environmental Protection Specialist
U.S. EPA, Office of Pesticide Programs,
Registration Division, Insecticide Branch
1200 Pennsylvania Avenue, NW (7504P)
Washington, DC 20460-0001
(703) 306-0327 (tel)
(703) 308-0029 (fax)
Rodia.Carmen@epa.gov

Deliveries: One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202-4501

Viewing Record 1 of 1



RE: Attached is the label review for 88966-R VETGUARD FOR CATS

Ann Tillman

to:

Richard Gebken

09/19/2012 08:34 AM

Cc:

Carmen Rodia

Hide Details

From: Ann Tillman <Ann@PyxisRC.com>

To: Richard Gebken/DC/USEPA/US@EPA

Cc: Carmen Rodia/DC/USEPA/US@EPA

2 Attachments



088966-xxxxR.2012919.VetGuard for Cats Label_changes tracked.pdf



088966-xxxxR.2012919.VetGuard for Cats Label.pdf

Richard,

Attached are the revised labels for the cat product—one version has the label changes tracked and the other is a clean copy.

I made the changes you required. The address for Tru Prodigy has changed so I made that change. Let me know if you need any other changes. Thanks.

Ann

Ann M. Tillman, Ph.D.
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332
Office (253) 853-7369
Fax (253) 853-5516
Email Ann@PyxisRC.com

From: Richard Gebken [<mailto:Gebken.Richard@epamail.epa.gov>]
Sent: Wednesday, September 12, 2012 11:31 AM
To: Ann Tillman
Cc: Carmen Rodia
Subject: Attached is the label review for 88966-R VETGUARD FOR CATS

Ann,

Please make the following changes to your label and return for completion on the PRIA due date. Also note, if you are making any changes other than the ones I've identified, you must provide a complete explanation as to the changes, and why they are necessary for us to consider.

Return your revised label by email to both Carmen Rodia and myself.

Regards,

Richard Gebken

(See attached file: Proposed label with Agency comments..pdf)

[Note to reviewer: optional text is placed in brackets]

[Package Insert, Text]

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil:.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:.....100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

~~[Does not wash off]~~ **Waterproof**

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills **adult** fleas]

[Kills newly emerged adult fleas prior to egg-laying]

~~[Stops existing infestations. Prevents break-out of new infestations]~~

[Effective treatment that kills **adult** fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, **and** anaplasmosis ~~and other tick-borne diseases~~]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills **adult** mosquitoes]

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

~~[Alternate text for bulk transport container label: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Only for repackaging into animal health products.]~~

~~[Alternate text for bulk transport container label: For Further Labeling and Repackaging Only. Not for Retail Sale or Use.]~~

[Package Insert, Text]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store unused product in original container only, out of reach of children and animals.

CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

~~[Alternate Storage and Disposal Text for bulk transport:~~

~~**Pesticide Storage:** Store in a cool dry place away from heat and open flame. Protect from freezing.~~

~~**Pesticide Disposal:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative of the nearest EPA Regional Office for guidance.~~

~~**Container Disposal: Outer Box:** Nonrefillable container. Do not reuse or refill this container. When completely empty offer for recycling if available or dispose of box in a sanitary landfill.~~

~~**Nonrefillable Container (greater than five gallons):** Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying; then offer for recycling, if available, or reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or by incineration or by other procedures approved by state and local authorities. Triple rinse containers small enough to shake (capacity <5 gallons) as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Pressure rinse as follows: Empty the remaining contents into application equipment or mix tank. Hold container upside down over application equipment or mix tank, or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.~~

~~**Refillable Container (greater than 55 gallons):** Refillable container. Refill this container with VetGuard for Cats only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. For final disposal, offer for recycling or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.~~

~~In case of minor spills or leaks, soak up with sand, earth or other suitable material and dispose of as pesticide waste.]~~

[Package Insert, Text]

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IF SWALLOWED: Immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Have the product container label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-888-314-8588 for emergency medical treatment information.

~~[Alternate text for bulk transport container label: CAUTION: Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.]~~

[Alternate text for bulk transport container label: ENVIRONMENTAL HAZARDS]

~~This product is toxic to birds, fish, and aquatic invertebrates. Do not apply directly to water. Do not contaminate water by cleaning equipment or disposal of wastes. Do not contaminate water when disposing of equipment washwaters.]~~

HAZARDS TO DOMESTIC ANIMALS

For external use only on cats. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using **ANY** pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. You may also contact **SAFETYCALL INTERNATIONAL** at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

Side Effects. After applying VetGuard for Cats, check your cat for side-effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea have been reported from grooming after treatment. If you observe these signs or symptoms in your treated cat, contact your veterinarian. You may also contact **SAFETYCALL INTERNATIONAL** at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame.

[Package Insert, Text]

VetGuard for Cats is approved for use on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks.

VetGuard for Cats keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

Frequency of Application

Monthly application of VetGuard for Cats ~~completely~~ controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days, ~~if needed~~.

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

Ticks: VetGuard for Cats kills ticks for at least one month. Apply VetGuard for Cats every 30 days to control ticks (larva, nymph and adult) that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, ~~and anaplasmosis and other tick-borne diseases~~.

Chewing Lice: VetGuard for Cats kills chewing lice for at least one month. Apply VetGuard for Cats every 30 days to control chewing lice.

Mosquitoes: Apply VetGuard for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 24 hours ~~(for up to 7 days)~~, and within 48 hours ~~(for up to 28 days)~~.

Use VetGuard for Cats on all cats including breeding, pregnant and lactating queens, and on kittens 8 weeks or older.

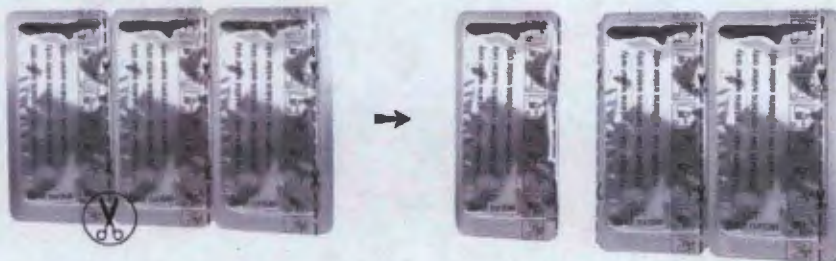
A one-spot application is convenient and easy for effective treatment of fleas, ticks, chewing lice, and mosquitoes. Apply VetGuard for Cats when your cat is dry.

VetGuard for Cat is applied at a single point on the surface of the skin between the cat's shoulders and rapidly covers the entire cat by localizing in the hair, on the surface of the skin and in the sebaceous glands.

Soon after coming into contact with a treated cat, fleas, ticks, mosquitoes, and chewing lice are ~~rapidly~~ killed. To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:

Remove and Open Package

- 1** Cut along scissor cut line to separate unit



- 2** Turn unit over and cut corner at bulb end



- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



[Package Insert, Text]

Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open.

Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.

ILLUSTRATIONS FOR APPLYING PRODUCT



LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of Tru Prodigy. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Tru Prodigy makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither Tru Prodigy, the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

EPA Reg. No.: 88966-R

EPA Est. No.:

Manufactured for:

Tru Prodigy
500 E. Shore Drive, Suite 130
Eagle, ID 83616-9417 Bredie Lane
Austin, TX 78748

[Made in Germany]

[VetGuard for Cats is a registered trade name of Tru Prodigy]

[Optional Bar Code]

[Optional text with Company logo]

[Carton Text - Front]

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil:.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:100.0%

Net Contents 0.21 Contains 3 0.017 fl. oz. (1.50-50 mL [3 tubes containing 0.017 fl. oz. each) applicators

3 Doses

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for First Aid and Precautionary Statements.

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

~~[Does not wash off]~~ Waterproof

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

~~[Stops existing infestations. Prevents break-out of new infestations]~~

[Effective treatment that kills fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, and anaplasmosis ~~and other tick borne diseases~~]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills adult mosquitoes]

[Kills fleas, ticks, chewing lice and ~~mosquitoes~~ mosquitoes]

~~[Company logo]~~



~~[Photo of cat]~~



[Pictogram of applicator]

[Picture of flea]

[Picture of tick]

[Picture of chewing lice]

[Picture of mosquitoes]

Manufactured for:

Tru Prodigy
500 E. Shore Drive, Suite 130
Eagle, ID 83616

[VetGuard for Cats is a registered trade name of Tru Prodigy]

EPA Reg. No. 88966-R

EPA Est. No.

[Made in Germany]

[Carton Text - Back]

VETGUARD FOR CATS

VetGuard for Cats ~~is approved for use~~ can be used on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks. VetGuard for Cats controls fleas, ticks, chewing lice and mosquitoes and keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

DIRECTIONS FOR USE

It is a violation of law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR CAT, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS OR ON OTHER ANIMALS.**

Side Effects. ~~See package insert for side effects. After applying VetGuard for Cats, check your cat for side effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea have been reported from grooming after treatment. If you observe these signs or symptoms in your treated cat, contact your veterinarian. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.~~

To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:

Remove and Open Package

See package insert for opening instructions.

Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open.

Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.



[ILLUSTRATIONS FOR APPLYING PRODUCT]

[Carton Text - Back]

Frequency of Application

Monthly application of VetGuard for Cats ~~completely~~ controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days, ~~if needed~~.

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

Ticks: VetGuard for Cats kills ticks for at least one month. Apply VetGuard for Cats every 30 days to control ticks (larva, nymph and adult) that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis ~~and other tick-borne diseases~~.

Chewing Lice: VetGuard for Cats kills chewing lice for at least one month. Apply VetGuard for Cats every 30 days to control chewing lice.

Adult Mosquitoes: Apply VetGuard for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 24 hours ~~(for up to 7 days)~~, and within 48 hours ~~(for up to 28 days)~~.

Manufactured for:

Tru Prodigy

500 E. Shore Drive, Suite 130
Eagle, ID 836169417 Brodie Lane
Austin, TX 78748

EPA Reg. No. 88966-R

EPA Est. No.

[Made in Germany]

[VetGuard for Cats is a registered trade name of Tru Prodigy]

[Carton Text – Front, Back, or Side Panel]

EPA Reg. No. 88966-R

EPA Est. No.

Batch/Lot No.

[Made in Germany]

[Insert with Tips, Front Side, Text]

[Optional marketing claims]

[Picture of flea]

[Picture of tick]

[Picture of chewing lice]

[Picture of mosquitoes]

VetGuard for Cats

See other side for stickers to remind you it's time to reapply VetGuard for Cats.

Some Tips and Other Information for Using VetGuard for Cats

Treat dogs and cats separately and only with the proper dose of VetGuard for Dogs or VetGuard for Cats.

Follow the label instructions for how to apply and be sure that VetGuard for Cats is applied to the skin, not on top of the fur and not near the collar. Removing the collar before application may help to prevent the collar from absorbing the VetGuard dose.

Apply VetGuard for Cats when your cat is dry. Make sure you apply all of the dose that is in the applicator.

Even indoor cats need flea and tick control if other household pets bring fleas into the home.

Fleas have many life stages and serious infestations can take up to 3 applications every 30 days for ~~complete~~ control. In fact, the flea life-cycle in the home can last as long as 21 days.

[Insert with Tips, Back Side, Text with Stickers]

Calendar Reminder Stickers

Reminder: It's time to repurchase VetGuard for Cats!

You can use these stickers to remind you when to apply and to purchase VetGuard for Cats.

The first time you treat your cat, peel off the sticker and place on your calendar that day. To remind you when the next application is due, place the other two stickers on your calendar 1 and 2 months after the first application.

3 Months

Sticker 1: Apply VetGuard for Cats

Sticker 2: Apply VetGuard for Cats

Sticker 3: Apply VetGuard for Cats

For Customer Service call 1-888-314-8588.

[For more information, visit www.xxxxx.com]

Tru Prodigy

Tru Prodigy

500 E. Shore Drive, Suite 130

Eagle, ID 83616



[Optional Company logo]

[Optional Bar code]

[Pictogram of Back of Blister With Opening Instructions]



[Text for Back of Blister]

KEEP Peep OUT ut OF ef REACH each OF ef CHILDREN hildren

CAUTION: See full label for additional instructions and precautions before using

Only for Cats & Kittens

VetGuard for Cats

EPA Reg. No. 88966-R

Lot/Batch No.

0.017 fl. oz. (0.5 mL)

9.7% Fipronil

1

[Pictogram of Front of Blister With Opening Instructions—NOT PART OF LABEL]



[Note to reviewer: optional text is placed in brackets]

[Package Insert, Text]

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil:.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:.....100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

[Waterproof]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Effective treatment that kills adult fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, and anaplasmosis]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills adult mosquitoes]

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

[Package Insert, Text]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store unused product in original container only, out of reach of children and animals.

CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IF SWALLOWED: Immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Have the product container label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-888-314-8588 for emergency medical treatment information.

HAZARDS TO DOMESTIC ANIMALS

For external use only on cats. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using **ANY** pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

Side Effects. After applying VetGuard for Cats, check your cat for side-effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea have been reported from grooming after treatment. If you observe these signs or symptoms in your treated cat, contact your veterinarian. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent

[Package Insert, Text]

veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame.

VetGuard for Cats is approved for use on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks.

VetGuard for Cats keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

Frequency of Application

Monthly application of VetGuard for Cats controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days.

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

Ticks: VetGuard for Cats kills ticks for at least one month. Apply VetGuard for Cats every 30 days to control ticks (larva, nymph and adult) that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis.

Chewing Lice: VetGuard for Cats kills chewing lice for at least one month. Apply VetGuard for Cats every 30 days to control chewing lice.

Mosquitoes: Apply VetGuard for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Use VetGuard for Cats on all cats including breeding, pregnant and lactating queens, and on kittens 8 weeks or older.

A one-spot application is convenient and easy for effective treatment of fleas, ticks, chewing lice, and mosquitoes. Apply VetGuard for Cats when your cat is dry.

VetGuard for Cat is applied at a single point on the surface of the skin between the cat's shoulders and rapidly covers the entire cat by localizing in the hair, on the surface of the skin and in the sebaceous glands.

Soon after coming into contact with a treated cat, fleas, ticks, mosquitoes, and chewing lice are killed. To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:

[Package Insert, Text]

Remove and Open Package

- 1** Cut along scissor cut line to separate unit



- 2** Turn unit over and cut corner at bulb end



- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open.

Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.



LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

[Package Insert, Text]

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of Tru Prodigy. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Tru Prodigy makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither Tru Prodigy, the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

EPA Reg. No.: 88966-R

EPA Est. No.:

Manufactured for:

Tru Prodigy
500 E. Shore Drive, Suite 130
Eagle, ID 83616

[Made in Germany]

[VetGuard for Cats is a registered trade name of Tru Prodigy]

[Optional Bar Code]

[Carton Text - Front]

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil:.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:100.0%

Net Contents 0.21 fl. oz. (1.5 mL [3 tubes containing 0.017 fl. oz. each])

3 Doses

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for First Aid and Precautionary Statements.

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

[Waterproof]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Effective treatment that kills fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, and anaplasmosis]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills adult mosquitoes]

[Kills fleas, ticks, chewing lice and mosquitoes]





Manufactured for:

Tru Prodigy
500 E. Shore Drive, Suite 130
Eagle, ID 83616

[VetGuard for Cats is a registered trade name of Tru Prodigy]

EPA Reg. No. 88966-R

EPA Est. No.

[Made in Germany]

[Carton Text - Back]

VETGUARD FOR CATS

VetGuard for Cats can be used on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks. VetGuard for Cats controls fleas, ticks, chewing lice and mosquitoes and keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

DIRECTIONS FOR USE

It is a violation of law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR CAT, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS OR ON OTHER ANIMALS.**

Side Effects. See package insert for side effects.

To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:

Remove and Open Package

See package insert for opening instructions.

Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open.

Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.



[Carton Text - Back]

Frequency of Application

Monthly application of VetGuard for Cats controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days.

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

Ticks: VetGuard for Cats kills ticks for at least one month. Apply VetGuard for Cats every 30 days to control ticks (larva, nymph and adult) that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis .

Chewing Lice: VetGuard for Cats kills chewing lice for at least one month. Apply VetGuard for Cats every 30 days to control chewing lice.

Adult Mosquitoes: Apply VetGuard for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Manufactured for:
Tru Prodigy
500 E. Shore Drive, Suite 130
Eagle, ID 83616

EPA Reg. No. 88966-R

EPA Est. No.

[Made in Germany]

[VetGuard for Cats is a registered trade name of Tru Prodigy]

[Carton Text – Front, Back, or Side Panel]

EPA Reg. No. 88966-R

EPA Est. No.

Batch/Lot No.

[Made in Germany]

[Insert with Tips, Front Side, Text]

[Optional marketing claims]

VetGuard for Cats

See other side for stickers to remind you it's time to reapply VetGuard for Cats.

Some Tips and Other Information for Using VetGuard for Cats

Treat dogs and cats separately and only with the proper dose of VetGuard for Dogs or VetGuard for Cats.

Follow the label instructions for how to apply and be sure that VetGuard for Cats is applied to the skin, not on top of the fur and not near the collar. Removing the collar before application may help to prevent the collar from absorbing the VetGuard dose.

Apply VetGuard for Cats when your cat is dry. Make sure you apply all of the dose that is in the applicator.

Even indoor cats need flea and tick control if other household pets bring fleas into the home.

Fleas have many life stages and serious infestations can take up to 3 applications every 30 days for control. In fact, the flea life-cycle in the home can last as long as 21 days.

[Insert with Tips, Back Side, Text with Stickers]

Calendar Reminder Stickers

Reminder: It's time to repurchase VetGuard for Cats!

You can use these stickers to remind you when to apply and to purchase VetGuard for Cats.

The first time you treat your cat, peel off the sticker and place on your calendar that day. To remind you when the next application is due, place the other two stickers on your calendar 1 and 2 months after the first application.

3 Months

Sticker 1: Apply VetGuard for Cats

Sticker 2: Apply VetGuard for Cats

Sticker 3: Apply VetGuard for Cats

For Customer Service call 1-888-314-8588.

[For more information, visit www.xxxx.com]

Tru Prodigy

Tru Prodigy

500 E. Shore Drive, Suite 130
Eagle, ID 83616



[Optional Bar code]

[Pictogram of Back of Blister With Opening Instructions]



[Text for Back of Blister]

KEEP OUT OF REACH OF CHILDREN

CAUTION: See full label for additional instructions and precautions before using

Only for Cats & Kittens

VetGuard for Cats

EPA Reg. No. 88966-R

Lot/Batch No.

0.017 fl. oz. (0.5 mL)

9.7% Fipronil



Fw: Attached is the label review for 88966-O VETGUARD FOR CATS

Carmen Rodia

to:

Carmen Rodia

09/13/2012 03:01 PM

Hide Details

From: Carmen Rodia [REDACTED]

To: Carmen Rodia/DC/USEPA/US@EPA

Please respond to Carmen Rodia [REDACTED]

1 Attachment



image001.gif

----- Forwarded Message -----

From: Richard Gebken <Gebken.Richard@epamail.epa.gov>

To: Ann Tillman <Ann@PyxisRC.com>; Carmen Rodia [REDACTED]

Sent: Thursday, September 13, 2012 2:02 PM

Subject: Re: Attached is the label review for 88966-O VETGUARD FOR CATS

Yes Ann, the date is the same. I'll have the DERs for you tomorrow, and hopefully the marked up label saturday.

Richard Gebken

Sent by EPA Wireless E-Mail Services..

From: Ann Tillman [Ann@PyxisRC.com]

Sent: 09/13/2012 08:06 AM MST

To: Carmen Rodia

Cc: Richard Gebken

Subject: RE: Attached is the label review for 88966-O VETGUARD FOR CATS

Thanks Carmen. I assume the same date applies for 88966-I, Vetguard for Dogs?

Ann

From: Carmen Rodia [mailto:Rodia.Carmen@epamail.epa.gov]

Sent: Thursday, September 13, 2012 10:57 AM

To: Ann Tillman
Cc: Richard Gebken
Subject: RE: Attached is the label review for 88966-R VETGUARD FOR CATS

Ann, the PRIA conclusion date for the referenced pending application is September 22, 2012. Regards, Carmen Rodia.

Carmen J. Rodia, Jr.
Environmental Protection Specialist
U.S. EPA, Office of Pesticide Programs,
Registration Division, Insecticide Branch
1200 Pennsylvania Avenue, NW (7504P)
Washington, DC 20460-0001
(703) 306-0327 (tel)
(703) 308-0029 (fax)
Rodia.Carmen@epa.gov

Deliveries: One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202-4501

▼ Ann Tillman —09/12/2012 03:04:32 PM—Richard, Can you tell me the exact PRIA due date?

From: Ann Tillman <Ann@PyxisRC.com>
To: Richard Gebken/DC/USEPA/US@EPA
Cc: Carmen Rodia/DC/USEPA/US@EPA
Date: 09/12/2012 03:04 PM
Subject: RE: Attached is the label review for 88966-R VETGUARD FOR CATS

Richard,

Can you tell me the exact PRIA due date?

I've reviewed your comments and don't have any questions. TruProdigy is going to provide me with pictograms for the label and once I have them I can insert and send the revised labels.
Thanks.

Ann

From: Richard Gebken [<mailto:Gebken.Richard@epamail.epa.gov>]
Sent: Wednesday, September 12, 2012 11:31 AM
To: Ann Tillman
Cc: Carmen Rodia
Subject: Attached is the label review for 88966-R VETGUARD FOR CATS
Ann,

Please make the following changes to your label and return for completion on the PRIA due date. Also note, if you are making any changes other than the ones I've identified, you must provide a complete explanation as to the changes, and why they are necessary for us to consider.

Return your revised label by email to both Carmen Rodia and myself.

Regards,

Richard Gebken

(See attached file: Proposed label with Agency comments..pdf)



Fw: Attached is the label review for 88966-R VETGUARD FOR CATS

Richard Gebken to: Carmen Rodia

09/20/2012 11:32 AM

From: Richard Gebken/DC/USEPA/US
To: Carmen Rodia/DC/USEPA/US@EPA

Cat product marked up copy of label you requested.

Richard

— Forwarded by Richard Gebken/DC/USEPA/US on 09/20/2012 11:32 AM —

From: Richard Gebken/DC/USEPA/US
To: Ann Tillman <Ann@PyxisRC.com>
Cc: Carmen Rodia/DC/USEPA/US@EPA
Date: 09/12/2012 11:30 AM
Subject: Attached is the label review for 88966-R VETGUARD FOR CATS

Ann,

Please make the following changes to your label and return for completion on the PRIA due date. Also note, if you are making any changes other than the ones I've identified, you must provide a complete explanation as to the changes, and why they are necessary for us to consider.

Return your revised label by email to both Carmen Rodia and myself.

Regards,

Richard Gebken



Proposed label with Agency comments..pdf

[Note to reviewer: optional text is placed in brackets]

[Package Insert, Text]

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:.....100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

[Does not wash off]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Stops existing infestations. Prevents break-out of new infestations]

[Effective treatment that kills fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills mosquitoes]

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

~~[Alternate text for bulk transport container label: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Only for repackaging into animal health products.]~~

~~[Alternate text for bulk transport container label: For Further Labeling and Repackaging Only. Not for Retail Sale or Use.]~~

[Package Insert, Text]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store unused product in original container only, out of reach of children and animals.

CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[Alternate Storage and Disposal Text for bulk transport:

~~Pesticide Storage: Store in a cool dry place away from heat and open flame. Protect from freezing.~~

~~Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative of the nearest EPA Regional Office for guidance.~~

~~Container Disposal: Outer Box: Nonrefillable container. Do not reuse or refill this container. When completely empty offer for recycling if available or dispose of box in a sanitary landfill.~~

~~Nonrefillable Container (greater than five gallons): Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying; then offer for recycling, if available, or reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or by incineration or by other procedures approved by state and local authorities. Triple rinse containers small enough to shake (capacity <5 gallons) as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container $\frac{1}{2}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Pressure rinse as follows: Empty the remaining contents into application equipment or mix tank. Hold container upside down over application equipment or mix tank, or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.~~

~~Refillable Container (greater than 55 gallons): Refillable container. Refill this container with VetGuard for Cats only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. For final disposal, offer for recycling or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.~~

~~In case of minor spills or leaks, soak up with sand, earth or other suitable material and dispose of as pesticide waste.]~~

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IF SWALLOWED: Immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

[Package Insert, Text]

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS

CAUTION: Harmful if swallowed. ~~Causes eye irritation.~~ Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

~~[Alternate text for bulk transport container label: CAUTION: Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.]~~

~~[Alternate text for bulk transport container label: ENVIRONMENTAL HAZARDS~~

~~This product is toxic to birds, fish, and aquatic invertebrates. Do not apply directly to water. Do not contaminate water by cleaning equipment or disposal of wastes. Do not contaminate water when disposing of equipment washwaters.]~~

HAZARD TO DOMESTIC ANIMALS

For external use only on cats. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using **ANY** pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. You may also contact SAFETYCALL INTERNATIONAL at 1-1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

Side Effects. After applying VetGuard for Cats, check your cat for side-effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea have been reported from grooming after treatment. If you observe these signs or symptoms in your treated cat, contact your veterinarian. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame.

VetGuard for Cats is approved for use on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks.

VetGuard for Cats keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

Frequency of Application

Monthly application of VetGuard for Cats **completely** controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days, ~~if needed.~~

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

[Package Insert, Text]

Ticks: VetGuard for Cats kills ticks for at least one month. Apply VetGuard for Cats every 30 days to control ticks (larva, nymph and adult) that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, anaplasmosis ~~and other tick-borne diseases~~.

Chewing Lice: VetGuard for Cats kills chewing lice for at least one month. Apply VetGuard for Cats every 30 days to control chewing lice.

Mosquitoes: Apply VetGuard for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 24 hours (for up to 7 days), and within 48 hours (for up to 28 days).

Use VetGuard for Cats on all cats including breeding, pregnant and lactating queens, and on kittens 8 weeks or older.

A one-spot application is convenient and easy for effective treatment of fleas, ticks, chewing lice, and mosquitoes. Apply VetGuard for Cats when your cat is dry.

VetGuard for Cat is applied at a single point on the surface of the skin between the cat's shoulders and rapidly covers the entire cat by localizing in the hair, on the surface of the skin and in the sebaceous glands.

Soon after coming into contact with a treated cat, fleas, ticks, mosquitoes, and chewing lice are ~~rapidly~~ killed. To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:

Remove and Open Package

- ① Cut along scissor cut line to separate unit



- ② Turn unit over and cut corner at bulb end

- ③ From cut corner, peel backing completely off from bottom to top

- ④ Remove the applicator



[Package Insert, Text]

Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open.

Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.

[ILLUSTRATIONS FOR APPLYING PRODUCT]

LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of Tru Prodigy. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Tru Prodigy makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither Tru Prodigy, the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

EPA Reg. No.: 88966-

EPA Est. No.:

Manufactured for:

Tru Prodigy
9417 Brodie Lane
Austin, TX 78748

[Made in Germany]

[VetGuard for Cats is a registered trade name of Tru Prodigy]

[Optional Bar Code]

[Optional text with Company logo]

[Carton Text - Front]

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil:.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:.....100.0%

Contains 3 0.017 fl. oz. (0.50 mL) applicators

3 Doses

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for First Aid and Precautionary Statements.

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

~~[Does not wash-off]~~

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

~~[Kills fleas]~~

[Kills newly emerged adult fleas prior to egg-laying]

~~[Stops existing infestations. Prevents break-out of new infestations]~~

[Effective treatment that kills fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

~~[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases]~~

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

~~[Kills mosquitoes]~~

[Kills fleas, ticks, chewing lice and mosquitoes]

[Company logo]

[Photo of cat]

[Pictogram of applicator]

[Picture of flea]

[Picture of tick]

[Picture of chewing lice]

[Picture of mosquitoes]

[Carton Text - Back]

VETGUARD FOR CATS

VetGuard for Cats ~~is approved for use~~ on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks. VetGuard for Cats controls fleas, ticks, chewing lice and mosquitoes and keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

DIRECTIONS FOR USE

It is a violation of law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR CAT, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS OR ON OTHER ANIMALS.**

~~Side Effects. After applying VetGuard for Cats, check your cat for side-effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea have been reported from grooming after treatment. If you observe these signs or symptoms in your treated cat, contact your veterinarian. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.~~

To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:

Remove and Open Package

See package insert for opening instructions.

Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open.

Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.

[ILLUSTRATIONS FOR APPLYING PRODUCT]

[Carton Text - Back]

Frequency of Application

Monthly application of VetGuard for Cats **completely** controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days, **if needed**.

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

Ticks: VetGuard for Cats kills ticks for at least one month. Apply VetGuard for Cats every 30 days to control ticks (larva, nymph and adult) that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, anaplasmosis **and other tick-borne diseases**.

Chewing Lice: VetGuard for Cats kills chewing lice for at least one month. Apply VetGuard for Cats every 30 days to control chewing lice.

Mosquitoes: Apply VetGuard for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 24 hours (for up to 7 days), and within 48 hours (for up to 28 days).

Manufactured for:
Tru Prodigy
9417 Brodie Lane
Austin, TX 78748

[VetGuard for Cats is a registered trade name of Tru Prodigy]

[Carton Text – Front, Back, or Side Panel]

EPA Reg. No. 88966-

EPA Est. No.

Batch/Lot No.

[Made in Germany]

[Insert with Tips, Front Side, Text]

[Optional marketing claims]

[Picture of flea]

[Picture of tick]

[Picture of chewing lice]

[Picture of mosquitoes]

VetGuard for Cats

See other side for stickers to remind you it's time to reapply VetGuard for Cats.

Some Tips and Other Information for Using VetGuard for Cats

Treat dogs and cats separately and only with the proper dose of VetGuard for Dogs or VetGuard for Cats.

Follow the label instructions for how to apply and be sure that VetGuard for Cats is applied to the skin, not on top of the fur and not near the collar. Removing the collar before application may help to prevent the collar from absorbing the VetGuard dose.

Apply VetGuard for Cats when your cat is dry. Make sure you apply all of the dose that is in the applicator.

Even indoor cats need flea and tick control if other household pets bring fleas into the home.

Fleas have many life stages and serious infestations can take up to 3 applications every 30 days for complete control. In fact, the flea life-cycle in the home can last as long as 21 days.

[Insert with Tips, Back Side, Text with Stickers]

Calendar Reminder Stickers

Reminder: It's time to repurchase VetGuard for Cats!

You can use these stickers to remind you when to apply and to purchase VetGuard for Cats.

The first time you treat your cat, peel off the sticker and place on your calendar that day. To remind you when the next application is due, place the other two stickers on your calendar 1 and 2 months after the first application.

3 Months

Sticker 1: Apply VetGuard for Cats

Sticker 2: Apply VetGuard for Cats

Sticker 3: Apply VetGuard for Cats

For Customer Service call 1-888-314-8588.

[For more information, visit www.xxxxx.com]

Tru Prodigy

[Optional Company logo]

[Optional Bar code]

[Pictogram of Back of Blister With Opening Instructions]



[Text for Back of Blister]

Keep Out of Reach of Children

CAUTION: See full label for additional instructions and precautions before using

Only for Cats & Kittens

VetGuard for Cats

EPA Reg. No. 88966-

Lot/Batch No.

0.017 fl. oz. (0.5 mL)

9.7% Fipronil

1
[Pictogram of Front of Blister With Opening Instructions – NOT PART OF LABEL]





Fw: Metaldehyde First Team Meeting, PP# 2E8070
Rosanna Louie-Juzwiak to: Marianne Lewis

09/20/2012 11:09 AM

Hi Marianne,

I hope all is well with you. I wanted to ask if you know if a label checklist and/or use summary table has been made available for this action, or would be in the works?

Thanks and see you next week,
Rosanna

— Forwarded by Rosanna Louie-Juzwiak/DC/USEPA/US on 09/20/2012 11:08 AM —



Metaldehyde First Team Meeting, PP# 2E8070

Tue 09/25/2012 2:00 PM - 3:00 PM

Attendance is for Rosanna Louie-Juzwiak

Chair: **Laura Nollen/DC/USEPA/US**

Rooms: RD Small Conference Room D - S-7771/Potomac Yard One@EPA



This entry has an alarm. The alarm will go off before the entry starts.

Required:

Amy Blankinship/DC/USEPA/US@EPA, Barbara Madden/DC/USEPA/US@EPA, Dana Spatz/DC/USEPA/US@EPA, Marianne Lewis/DC/USEPA/US@EPA, Melanie Biscoe/DC/USEPA/US@EPA, Michael Metzger/DC/USEPA/US@EPA, Rosanna Louie-Juzwiak/DC/USEPA/US@EPA, Venus Eagle/DC/USEPA/US@EPA

Optional:

Jill Bloom/DC/USEPA/US@EPA, Meredith Laws/DC/USEPA/US@EPA

Description



Metaldehyde New Use Team Meeting.docx All,

This is a first team meeting for the recently submitted IR-4 action, petition #2E8070, for the use of metaldehyde on grass, leaf petioles subgroup 4B, mint, Berry subgroups 13-07 A, B, & G, taro, corn (sweet and field) and soybean.

We will discuss any anticipated issues associated with the chemical/action during the meeting.


Please let me know who else to invite. Please also let me know if you would like to add any items to the meeting agenda, which I will circulate about a week prior to the meeting.

If you have any questions, feel free to contact me.

Regards,

Laura
305-7390



RE: Attached is the label review for 88966-R VETGUARD FOR CATS 

Carmen Rodia to: Ann Tillman

09/13/2012 10:56 AM

Cc: Richard Gebken

Bcc: Carmen Rodia

From: Carmen Rodia/DC/USEPA/US
To: Ann Tillman <Ann@PyxisRC.com>
Cc: Richard Gebken/DC/USEPA/US@EPA
Bcc: Carmen Rodia/DC/USEPA/US

Ann, the PRIA conclusion date for the referenced pending application is September 22, 2012. Regards,
Carmen Rodia.

Carmen J. Rodia, Jr.
Environmental Protection Specialist
U.S. EPA, Office of Pesticide Programs,
Registration Division, Insecticide Branch
1200 Pennsylvania Avenue, NW (7504P)
Washington, DC 20460-0001
(703) 306-0327 (tel)
(703) 308-0029 (fax)
Rodia.Carmen@epa.gov

Deliveries: One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202-4501

Ann Tillman

Richard, Can you tell me the exact PRIA due date?

09/12/2012 03:04:32 PM

From: Ann Tillman <Ann@PyxisRC.com>
To: Richard Gebken/DC/USEPA/US@EPA
Cc: Carmen Rodia/DC/USEPA/US@EPA
Date: 09/12/2012 03:04 PM
Subject: RE: Attached is the label review for 88966-R VETGUARD FOR CATS

Richard,

Can you tell me the exact PRIA due date?

I've reviewed your comments and don't have any questions. TruProdigy is going to provide me with pictograms for the label and once I have them I can insert and send the revised labels.
Thanks.

Ann

From: Richard Gebken [mailto:Gebken.Richard@epamail.epa.gov]
Sent: Wednesday, September 12, 2012 11:31 AM
To: Ann Tillman
Cc: Carmen Rodia
Subject: Attached is the label review for 88966-R VETGUARD FOR CATS

Ann,

Please make the following changes to your label and return for completion on the PRIA due date. Also note, if you are making any changes other than the ones I've identified, you must provide a complete explanation as to the changes, and why they are necessary for us to consider.

Return your revised label by email to both Carmen Rodia and myself.

Regards,

Richard Gebken

(See attached file: Proposed label with Agency comments..pdf)



Attached is the label review for 88966-R VETGUARD FOR CATS

Richard Gebken to: Ann Tillman

09/12/2012 11:30 AM

Cc: Carmen Rodia

From: Richard Gebken/DC/USEPA/US
To: Ann Tillman <Ann@PyxisRC.com>
Cc: Carmen Rodia/DC/USEPA/US@EPA

Ann,

Please make the following changes to your label and return for completion on the PRA due date. Also note, if you are making any changes other than the ones I've identified, you must provide a complete explanation as to the changes, and why they are necessary for us to consider.

Return your revised label by email to both Carmen Rodia and myself.

Regards,

Richard Gebken



Proposed label with Agency comments...pdf

[Note to reviewer: optional text is placed in brackets]

[Package Insert, Text]

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:.....100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

[Does not wash off]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Kills fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Stops existing infestations. Prevents break-out of new infestations]

[Effective treatment that kills fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases]

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills mosquitoes]

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

~~[Alternate text for bulk transport container label: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Only for repackaging into animal health products.]~~

~~[Alternate text for bulk transport container label: For Further Labeling and Repackaging Only. Not for Retail Sale or Use.]~~

[Package Insert, Text]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store unused product in original container only, out of reach of children and animals.

CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

~~[Alternate Storage and Disposal Text for bulk transport:~~

~~Pesticide Storage: Store in a cool dry place away from heat and open flame. Protect from freezing.~~

~~Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative of the nearest EPA Regional Office for guidance.~~

~~Container Disposal: Outer Box: Nonrefillable container. Do not reuse or refill this container. When completely empty offer for recycling if available or dispose of box in a sanitary landfill.~~

~~Nonrefillable Container (greater than five gallons): Do not reuse or refill this container. Triple-rinse or pressure-rinse container (or equivalent) promptly after emptying; then offer for recycling, if available, or reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or by incineration or by other procedures approved by state and local authorities. Triple-rinse containers small enough to shake (capacity <5 gallons) as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/2 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Pressure-rinse as follows: Empty the remaining contents into application equipment or mix tank. Hold container upside down over application equipment or mix tank, or collect rinsate for later use or disposal. Insert pressure-rinsing nozzle in the side of the container and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.~~

~~Refillable Container (greater than 55 gallons): Refillable container. Refill this container with VetGuard for Cats only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. For final disposal, offer for recycling or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.~~

~~In case of minor spills or leaks, soak up with sand, earth or other suitable material and dispose of as pesticide waste.]~~

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IF SWALLOWED: Immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

[Package Insert, Text]

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS

CAUTION: Harmful if swallowed. ~~Causes eye irritation.~~ Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

~~[Alternate text for bulk transport container label: CAUTION: Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.]~~

~~[Alternate text for bulk transport container label: ENVIRONMENTAL HAZARDS~~

~~This product is toxic to birds, fish, and aquatic invertebrates. Do not apply directly to water. Do not contaminate water by cleaning equipment or disposal of wastes. Do not contaminate water when disposing of equipment washwaters.]~~

HAZARD TO DOMESTIC ANIMALS

For external use only on cats. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using **ANY** pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. You may also contact SAFETYCALL INTERNATIONAL at 1-1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

Side Effects. After applying VetGuard for Cats, check your cat for side-effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea have been reported from grooming after treatment. If you observe these signs or symptoms in your treated cat, contact your veterinarian. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame.

VetGuard for Cats is approved for use on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks.

VetGuard for Cats keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

Frequency of Application

Monthly application of VetGuard for Cats **completely** controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days, ~~if needed.~~

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

[Package Insert, Text]

Ticks: VetGuard for Cats kills ticks for at least one month. Apply VetGuard for Cats every 30 days to control ticks (larva, nymph and adult) that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, anaplasmosis ~~and other tick-borne diseases~~.

Chewing Lice: VetGuard for Cats kills chewing lice for at least one month. Apply VetGuard for Cats every 30 days to control chewing lice.

Mosquitoes: Apply VetGuard for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 24 hours (for up to 7 days), and within 48 hours (for up to 28 days).

Use VetGuard for Cats on all cats including breeding, pregnant and lactating queens, and on kittens 8 weeks or older.

A one-spot application is convenient and easy for effective treatment of fleas, ticks, chewing lice, and mosquitoes. Apply VetGuard for Cats when your cat is dry.

VetGuard for Cat is applied at a single point on the surface of the skin between the cat's shoulders and rapidly covers the entire cat by localizing in the hair, on the surface of the skin and in the sebaceous glands.

Soon after coming into contact with a treated cat, fleas, ticks, mosquitoes, and chewing lice are ~~rapidly~~ killed. To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:

Remove and Open Package

- ① Cut along scissor cut line to separate unit



- ② Turn unit over and cut corner at bulb end



- ③ From cut corner, peel backing completely off from bottom to top



- ④ Remove the applicator



[Package Insert, Text]

Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open.

Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.

[ILLUSTRATIONS FOR APPLYING PRODUCT]

LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of Tru Prodigy. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Tru Prodigy makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither Tru Prodigy, the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

EPA Reg. No.: 88966-

EPA Est. No.:

Manufactured for:

Tru Prodigy
9417 Brodie Lane
Austin, TX 78748

[Made in Germany]

[VetGuard for Cats is a registered trade name of Tru Prodigy]

[Optional Bar Code]

[Optional text with Company logo]

[Carton Text - Front]

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:.....100.0%

Contains 3.0-0.17 fl. oz. (9.50 mL) applicators

3 Doses

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for First Aid and Precautionary Statements.

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

~~[Does not wash off]~~

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

~~[Kills fleas]~~

[Kills newly emerged adult fleas prior to egg-laying]

~~[Stops existing infestations. Prevents break-out of new infestations]~~

[Effective treatment that kills fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

~~[Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases]~~

[Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

~~[Kills mosquitoes]~~

[Kills fleas, ticks, chewing lice and mosquitoes]

~~[Company logo]~~

[Photo of cat]

[Pictogram of applicator]

[Picture of flea]

[Picture of tick]

[Picture of chewing lice]

[Picture of mosquitoes]

[Carton Text - Back]

VETGUARD FOR CATS

VetGuard for Cats ~~is approved for use~~ on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks. VetGuard for Cats controls fleas, ticks, chewing lice and mosquitoes and keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

DIRECTIONS FOR USE

It is a violation of law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR CAT, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS OR ON OTHER ANIMALS.**

~~Side Effects. After applying VetGuard for Cats, check your cat for side effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea have been reported from grooming after treatment. If you observe these signs or symptoms in your treated cat, contact your veterinarian. You may also contact SAFETYGALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.~~

To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:

Remove and Open Package

See package insert for opening instructions.

Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open.

Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.

[ILLUSTRATIONS FOR APPLYING PRODUCT]

[Carton Text - Back]

Frequency of Application

Monthly application of VetGuard for Cats **completely** controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days, **if needed**.

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

Ticks: VetGuard for Cats kills ticks for at least one month. Apply VetGuard for Cats every 30 days to control ticks (larva, nymph and adult) that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, anaplasmosis **and other tick-borne diseases**.

Chewing Lice: VetGuard for Cats kills chewing lice for at least one month. Apply VetGuard for Cats every 30 days to control chewing lice.

Mosquitoes: Apply VetGuard for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 24 hours (for up to 7 days), and within 48 hours (for up to 28 days).

Manufactured for:
Tru Prodigy
9417 Brodie Lane
Austin, TX 78748

[VetGuard for Cats is a registered trade name of Tru Prodigy]

[Carton Text – Front, Back, or Side Panel]

EPA Reg. No. 88966-

EPA Est. No.

Batch/Lot No.

[Made in Germany]

[Insert with Tips, Front Side, Text]

[Optional marketing claims]

[Picture of flea]

[Picture of tick]

[Picture of chewing lice]

[Picture of mosquitoes]

VetGuard for Cats

See other side for stickers to remind you it's time to reapply VetGuard for Cats.

Some Tips and Other Information for Using VetGuard for Cats

Treat dogs and cats separately and only with the proper dose of VetGuard for Dogs or VetGuard for Cats.

Follow the label instructions for how to apply and be sure that VetGuard for Cats is applied to the skin, not on top of the fur and not near the collar. Removing the collar before application may help to prevent the collar from absorbing the VetGuard dose.

Apply VetGuard for Cats when your cat is dry. Make sure you apply all of the dose that is in the applicator.

Even indoor cats need flea and tick control if other household pets bring fleas into the home.

Fleas have many life stages and serious infestations can take up to 3 applications every 30 days for complete control. In fact, the flea life-cycle in the home can last as long as 21 days.

[Insert with Tips, Back Side, Text with Stickers]

Calendar Reminder Stickers

Reminder: It's time to repurchase VetGuard for Cats!

You can use these stickers to remind you when to apply and to purchase VetGuard for Cats.

The first time you treat your cat, peel off the sticker and place on your calendar that day. To remind you when the next application is due, place the other two stickers on your calendar 1 and 2 months after the first application.

3 Months

Sticker 1: Apply VetGuard for Cats

Sticker 2: Apply VetGuard for Cats

Sticker 3: Apply VetGuard for Cats

For Customer Service call 1-888-314-8588.

[For more information, visit www.xxxxx.com]

Tru Prodigy

[Optional Company logo]

[Optional Bar code]

[Pictogram of Back of Blister With Opening Instructions]



[Text for Back of Blister]

Keep Out of Reach of Children

CAUTION: See full label for additional instructions and precautions before using

Only for Cats & Kittens

VetGuard for Cats

EPA Reg. No. 88966-

Lot/Batch No.

0.017 fl. oz. (0.5 mL)

9.7% Fipronil

1

[Pictogram of Front of Blister With Opening Instructions – NOT PART OF LABEL]





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

August 14, 2012

MEMORANDUM

Subject: Name of Pesticide Product: VetGuard For Cats
EPA Reg. No. /File Symbol: 88966-R
DP Barcode: 401402
Decision No: 461924
Action Code: R310.1
PC Code: 129121 (Fipronil: 9.7%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
August -14- 2012
H. Backus, Ph.D.

To: Samantha Hulkower, RM 10
Insecticide Branch
Registration Division (7505P)

Registrant: TRU PRODIGY

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
129121 Fipronil	9.7
<u>Inert Ingredient(s):</u>	<u>90.3</u>
Total:	100.0

ACTION REQUESTED: The Risk Manager requests: "Please review the MRIDs cited to support the companion animal safety requirements for this product. The registrant has cited 65331-2 as substantially similar. I found one data package for a companion animal review - 282329..."

BACKGROUND: The material received for review includes a draft copy of the proposed product label (signal word: CAUTION) dated 2-28-2012, a data matrix dated March 30, 2012 which indicates (on p. 4) cite-all to the companion animal safety study (870.7200) requirements, and basic and alternate CSFs dated February 24, 2012.

COMMENTS AND RECOMMENDATIONS:

1. According to our records, the companion animal safety studies used to support the registration and uses of 65331-2 (and similar products) included (but were not necessarily limited to) the following: MRID 44942009 (Clery, D. (1999) Fipronil/(S)-Methoprene/Topical/Solution/Target Species Safety Study in the Cat: Interim Final Report: Lab Project Number: GB011/99-001: PR&D 0023301. Unpublished study prepared by Biological Labs. Europe Ltd. 127 p. {OPPTS 870.7200}); 43863801 (Cameron, D.; Maltby, B. (1995) Domestic Animal Safety by Topical Administration to Cats: Fipronil Spot Treatment: Lab Project Number: MRX 24/950746. Unpublished study prepared by Huntingdon Research Centre, Ltd. 174 p.). It is noted that in TXR 0011764 (a memorandum dated January 24, 1996 from Virginia A. Dobozy, V.M.D. of HED to Rick Keigwin/Ann Sibold of the Registration Division) there is a discussion in support of bridging domestic animal safety data on Frontline® Spot Treatment from Frontline® Spray Treatment, containing 0.25% w/v fipronil). After examining and comparing the CSFs for 88966-R and 65331-2, TRB has concluded that these studies (and possibly others) can be used to support the registration of 88966-R as a spot-on for use on cats.
2. The proposed label for EPA File Symbol 88966-R includes the statement: "VetGuard for Cats is approved for use on all cats including breeding, pregnant and lactating queens..." After examining and comparing the CSFs for 88966-R and 65331-2, TRB has concluded that we can accept this claim, based on the study in MRID 45618502 (Godin, C.; Alva, R. (2000) ML-2,095,988 508Q/Cat/Solution/Topical/Safety/Tolerance/Reproduction, Reactions: Final Report: Lab Project Number: PR&D 0020301: WEL 99886. Unpublished study prepared by White Eagle Toxicology Laboratory. 88 p.). TRB notes that the study in MRID 45618502 is not a conventional OCSPP (formerly OPPTS) 870.7200, and should be specifically cited to support this claim.
3. The proposed labeling for EPA File Symbol 88966-R includes statements [under Alternate Storage and Disposal Text for bulk transport:] regarding nonrefillable (>5 gallons) and refillable containers (>55 gallons). These statements are inappropriate because the end-use product as proposed for registration is in applicators each containing 0.50 mL of formulation.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

07/26/2012

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No. 88966-R

Product Name: VETGUARD FOR CATS
DP Barcode: 401395
Decision No: 461924
Action Code: R310-1
PC Code: 129121

From: Santa K Vinjamuri M.D., D.C.P. *Banta*
Inert Ingredient Assessment Branch (IIAB)
Registration Division (7505P)

Through: Masih Hashim, Team Leader-Toxicology *Hashim*
Technical Review Branch (TRB)
Registration Division (7505P)

To: Samantha Hulkower, RM Team 10
Insecticide Branch
Registration Division (7505P)

Applicant: Tru Prodigy
9417 Brodie Lane
Austin, TX 78748

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt</u>
Fipronil :	9.7
<u>Inert Ingredient(s):</u>	90.3
Total:	100.0

BACKGROUND: The Risk Manager requests that TRB review the acute toxicity studies for the proposed product containing ai Fipronil (9.7%).

Tru Prodigy (herein the "registrant") has submitted acute oral, dermal, inhalation, primary skin irritation, primary eye irritation, and dermal sensitization studies (MRID: 43951703 and MRIDs: 43577705 through 43577710) performed at Centre International de Toxicologie (CIT) and Inveresk Research International LTD in support of registration of their product, "Vetguard for Cats", EPA File Symbol: 88966-R. Included in the data package were the study volumes, basic CSF (dated 02/24/2012), proposed label and letter from the registrant. These studies were reviewed by RSB/RD on 07/17/1995.

In all these studies two substances, 1.) RM160IE/62 and 2.) RM160IE/64 were used as test material. After careful review of analysis report it is evident that RM160IE/64 is a control substance as it contains 0.0% Fipronil. The tests done with RM160IE/62 were taken into consideration as it contains 9.7% Fipronil (the subject product) and all the tests are upgraded in the present review according to the current requirements.

The label claims that the product "Vetguard for Cats" is for use only on cats & kittens (8 weeks and older) for monthly control of fleas, ticks, chewing lice and mosquitoes.

1. The Basic Formulation CSF dated 02/24/2012 for the proposed product should also be reviewed and accepted by the TRB Product Chemistry Team.
2. Based on the toxicity profile, the following are the precautionary and first aid statements for this product as obtained from the Label Review System.

Continued on the next page

Precautionary Labeling:

Product Reg. No.: 0088966-R (00001)

Product Name: VETGUARD FOR CATS

Signal Word: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Avoid contact with skin or clothing. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

→ Not applicable since this is a residential use product
R. Gersh 9/7/2012

DATA EVALUATION RECORD

Product Reg. No.: 88966-R

Product Name: VETGUARD FOR CATS

1. DP BARCODE: 401395				
2. PC CODE: 129121				
3. CURRENT DATE: 07/26/2012				
4. TEST MATERIAL: RM160IE/62 and RM1601E/64. yellowish liquid, Batch NO: J0700 & J0701				
Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Grade
Acute oral toxicity / rat/ Centre International de Toxicologie, CIT Project ID: 2781TAR/ 2 nd March 1994, / September 17 th 2002. 2. Project ID: 13450 TAR/ February 29, 1996	43577705	Oral LD ₅₀ mg/kg in rats- for RM160IE/62 > 5000 for RM1601E/64: males: 3208 (1730-8608) females: 2821 (1445-14546), combined: 2995 (1996-5657) mg/kg. Clinical signs: hypoactivity, sedation, piloerection at all doses in both sexes, dyspnoea in males at 2000 & in both sexes at 5000 mg/kg. - Mortality: 1000 mg/kg 2000 mg/kg 5000 mg/kg 0/5 M 1/5 F 1/5 M 1/5 F 4/5 M 4/5 F Oral LD ₅₀ mg/kg for RM160IE/62 Male rats: 2515 (1446-5020) mg/kg, female rats: 3259 (1869-8371) mg/kg combined: 2863 (1979-4559) mg/kg	III	A
Acute dermal toxicity / rat/ Centre International de Toxicologie, CIT Project ID: 2008TAR / November 25 th 1994	43577706	LD ₅₀ > 5,000 mg/kg in male and female rats. Hypoactivity was observed in one male and three female rats but recovered by day 2.	IV	A
Acute inhalation toxicity / rat / Inveresk Research International LTD Project ID: IRI 654387/ March 10 th 1995.	43577707	LC ₅₀ . RM 1601E/62 was not established considered to be > 6.32 mg/L, RM 1601E/64 not established considered to be in excess of 5.72 mg/L MMAD: 3 µm GSD: ±1.91. Nominal Concentration Chamber Concentration 4.51-6.16 mg/L 6.32, 5.72 mg/L Temp Humidity Total air flow 20-22 °C 43 -57% 38.96 Lpm Clinical signs: Congested breathing and dark material around the facial area. Recovered by day 5. Deficiencies: Reason for not establishing LC ₅₀ not known. Not mentioned if Particle size is determined twice or not	IV	S
Primary eye irritation / rabbit/ Centre International de Toxicologie CIT Project ID: 2010TAL / 11/ 25/ 1994.	43577708	Moderately irritating to the eyes. Clearing in 7 days. RM 1601E/62: At 48 hrs-2/6 conjunctivitis & corneal opacity, 1/6 Iritis, at 72 hrs 1/6 corneal opacity resolved by day 5. RM 1601E/64: At 48 hrs-2/6 conjunctivitis clearing by 48 hrs.	III	A

Continued on the next page

<p>Primary dermal irritation / rabbit/ Centre International de Toxicologie CIT Project ID: 12009TAL / November 25th 1994.</p>	43577709	<p>Moderate irritation clearing in 72hours. Mean Irritation score RM 1601E/62 RM 1601E/64 Erythema/edema 0.8/0.0 1.7/0.0 RM 1601E/62: Slight to moderate erythema was noted on all animals on day I. All cleared from days 2 to 6. RM 1601E/64: Slight to moderate erythema in 5/6 & Moderate to marked erythema in 1 animal from days 1 to 5.</p>	III	A
<p>Dermal sensitization- Guinea pigs- Buehler) /Centre International de Toxicologie CIT Project ID: 12011TSG/ December 26th 1994</p>	43577710	<p>Negative (Non-sensitizer) 100% test article (RM1601E/62 to group 1 & RM1601E/64 to group 2) was used for induction & challenge During the induction period, slight erythema (grade 1) was observed on 2/20 of group 2 and 2/10 of group 3. No cutaneous reactions were seen in the control or test groups after challenge. Deficiencies: Positive response observed with DNCB for the test system validation was not done within 6 months of the study. (January 1994 (CIT/Study No. 11285 TSG)</p>	-	S

Grade Key: A =Acceptable, U = Unacceptable, D = Data Gap, S = Supplementary



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

FEE

BARCODE No.: 401382; **FILE SYMBOL No.:** 88966-R; **DECISION No.:** 461924;
PRODUCT NAME: Vetguard for Cats; **PC Code(s):** 129121; **ACTION CODE:** R310;

DATE: July 17, 2012

SUBJECT: Product Name: Vetguard for Cats

FROM: Akiva Abramovitch, Ph.D.
Technical Review Branch / RD (7505P)

THROUGH: Shyam B. Mathur, Ph.D.
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

TO: Richard Gebken, PM 10
Insecticide Branch/ RD (7505C)

Company Name: TRU PRODIGY
Formulation Type: Liquid solution

INTRODUCTION:

The applicant has submitted an application for registration of a new end use product. In support of the registration application, the registrant has submitted product chemistry data corresponding to guideline 830 series, group A & group B (MRIDs 487554-01, -02 and -03). The CSF of the basic CSF and alternate CSF #1 (dated 2/24/2012) were submitted along with the product label. TRB has been asked to determine the acceptability of the product chemistry data and the proposed basic and alternate #1 CSFs both dated February 24, 2012.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient: Fipronil (9.7%).
2. Has the registrant claimed substantial similarity to a registered product?

[X] Yes; [] No; [] NA; if yes give the registration number of the cited product.

EPA Reg. No. 65331-2

3. All the source materials for the active ingredients are derived from the registered sources:
[X] Yes; [] No.

BARCODE No.: 401382; **FILE SYMBOL No.:** 88966-R; **DECISION No.:** 461924;

PRODUCT NAME: Vetguard for Cats; **PC Code(s):** 129121; **ACTION CODE:** R310;

4. All inert ingredients have been screened by IIAB (and found to be approved for the proposed labeled uses: ☒ Yes; ☐ No.

5. Confidential Statement of Formula(s):

☒ Basic Dated: February 24, 2012;

☒ Alternate CSF #1 dated February 24, 2012

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product label (PR Notice 91-2).

☒ Yes, if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)?

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA;

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid equivalent: ☐ Yes ☒ NA; {name} acid equivalent = xx %

b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☒ No ☐ NA

Methanol at > 4%: ☐ Yes ☒ No ☐ NA

Sodium nitrate/Sodium nitrite ☐ Yes ☒ No ☐ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes, ☐ No, ☒ NA, if not, explain below:

d. Label requires an additional Storage and Disposal statement:

☐ Yes ☒ No

BARCODE No.: 401382; **FILE SYMBOL No.:** 88966-R; **DECISION No.:** 461924;

PRODUCT NAME: Vetguard for Cats; **PC Code(s):** 129121; **ACTION CODE:** R310;

7. Group A: Product Chemistry Data

TRB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	487554-01
830.1600	Description of materials used to produce the product		X		A	487554-01
830.1650	Description of formulation process		X		A	487554-01
830.1670	Discussion on the formation of impurities		X		A	487554-01
830.1700	Preliminary analysis			X	NA	
830.1750	Certified limits (158.350)	Standard certified Limits	X		A	487554-01
		Proposed Limits				
		Justification for wider limits			NA	
830.1800	Enforcement analytical method		X		A (HPLC method)	

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Colorless solution with an ester-like odor	A	487554-02
830.6315	Flammability	38.9° C	A	487554-02
830.6316	Explodability	NA, not considered to be potentially explosive	A	487554-02
830.7000	pH	5.41	A	487554-02
830.7300	Density (units)	1.0368 g/cm ³ at 20C	A	487554-02

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress, U = Upgradeable

BARCODE No.: 401382; **FILE SYMBOL No.:** 88966-R; **DECISION No.:** 461924;
PRODUCT NAME: Vetguard for Cats; **PC Code(s):** 129121; **ACTION CODE:** R310;

CONCLUSIONS:

TRB has reviewed the CSF(s) and product chemistry data for the proposed end use product and has concluded:


1. The proposed CSFs for the basic and alternate formulations both dated 2/24/2012) are acceptable.
2. The data submitted corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product)830.1650, (description of formulation process), 830.1670 (discussion on the formation of impurity), 830.1750 (certified limits), and 830.1800 (enforcement analytical method) are acceptable.
3. The product chemistry data submitted corresponding to guidelines 830.6302 (color), 830.6303 (physical state), 830.6304 (odor), 830.6314 (oxidation/reduction), 830.6315 (flammability), 830.6316 (explosibility), 830.7000 (viscosity), and 830.7300 (density) are acceptable.
4. The storage stability (guideline 830.6317) and corrosion characteristics (guideline 830.6320) data were not submitted. Studies are required and it is recommended that observations be made at 0, 3, 6, 9, and 12 month intervals.
5. The proposed label was screened as it pertains to the product chemistry requirements. The review of the proposed label and uses are the purview of the RM team.
6. This product is substantially similar to the cited product EPA Reg. No. 65331-2.

Efficacy Review

Date: June 21, 2012

Efficacy Reviewer: Clayton Myers, Ph.D., Entomologist, RD-IB
myers.clayton@epa.gov
703-347-8874

Risk Manager Rev.: Samantha Hulkower

 6-25-12

Products: Vetguard for Cats

EPA Reg. #: 88066-R

A.I.'s: Fipronil (9.7%)

Decision #s: 461924

DP #s: 401403

Submission: R310, New Products, RD Science Review

MRIDs: Cite-all for Efficacy

GLP: N/A

Summary/Discussion of Cited Efficacy Data:

Efficacy claims are supported for control the following pests on cats for one month:

1. Fleas (adults only). The six week duration claim is supported for fleas, as it is caveated that treatment should be applied every four weeks under high flea pressure (same as claims accepted for pioneer fipronil products).
2. Ticks, including ticks that may transmit Lyme disease
3. Mosquitoes
4. Chewing Lice

Overall Review of Label Claims and Directions:

1. Claims expressed as "complete" or referring to "completely controls" with regard to any listed pests must be deleted throughout the label, as this implies 100% efficacy.
2. With regard to the mosquito claim "mosquitoes are killed within 24 hours for up to 7 days and within 48 hours for up to 28 days", all parentheses must be removed, as this could indicate that part of the claim is optional text.
3. The product name "VetGuard" might be interpreted as misleading, as the Agency does not allow statements that imply veterinarian endorsement or enhanced efficacy—this labeling decision is deferred to the product manager (PM).

4. Claims for control of vectors that may transmit diseases must specifically list the disease(s) with no open ended notations such as "including" or "such as", which would imply efficacy against additional diseases that aren't specifically listed.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

CHILD-RESISTANT PACKAGING REVIEW
Technical Review Branch

IN 5/1/2012 OUT 6/4/2012

RD, TRB, Reviewed by Rosalind L. Gross

Rosalind L. Gross
6/4/2012

EPA Reg. No. or File Symbol 88966-E & 88966-R

DP Barcode DP401385, 400488

Decision # 461923, 461924

EPA Petition or EUP No. _____

Date Division Received 3/1/2012, 3/1/2012

Type Product(s) Insecticide (flea product)

Data Accession No(s). 48755301 (KVS-201106)

Product Mgr./Chemical Review Mgr/Contact Person RM 10 Samantha Hulkower
Division RD

Product Name(s) Vetguard for Dogs, Vetguard for Cats

Company Name(s) Tru Prodigy

Submission Purpose Review of CRP studies to determine if they are adequate to support CRP certification for these products

Active Ingredient(s), PC code, & % Fipronil 9.7%

Summary of Findings

**In conclusion all the requirements for CRP have been met for EPA
Registration No. 88966-E, 88966-R. The directions on opening the package given**

to consumers must be identical to those given to the seniors during testing (see packaging section below). For details see Analysis of Data and Conclusions section below.

Should any human experience/epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.

Package

The package is a pipette in a blister. The pipette has clear plastic front and foil backing. The blister is the Child-Resistant Packaging, CRP. The blister backing is PET/AL/PET/PE 12/12/12/75, which appears as a foil color. The blister front is PET/PP/PE transp. LDPE 350/100/75, which appears as a clear color. Three blisters are attached to each other to form one card. There are 5 fill volumes 0.67ml, 1.34ml, 2.68ml, 4.02ml, and 0.5ml.

The Senior Adult Use Effectiveness Testing, SAUE, directions on the back of the blister are a pictorial showing the separation of one of the three attached blisters and removing the pipette from the blister that repeats for the height of the blister and a dashed line with a picture of a scissors to the right of the pictorial showing where to separate one of the three attached blisters (see picture below). In addition to the SAUE directions on the back of the blister, there are also SAUE directions in a leaflet that were given to the test subjects. There is a set of instructions used for all 5 fill volumes, which is referred to in this review as Package Instructions for SAUE Testing Set 2 (see picture below for set of SAUE Testing directions). EPA Registration No. 88966-E is for fill volumes 0.67ml, 1.34ml, 2.68ml, 4.02ml. EPA Registration No. 88966-R is fill volume 0.5ml.



Back of Blister with Opening Instructions

Opening Instructions from Package Leaflet

OPENING INSTRUCTIONS FOR USE

- 1** Cut along scissor cut line to separate unit

- 2** Turn unit over and cut corner at bulb end

- 3** From cut corner, peel backing completely off from bottom to top

- 4** Remove the applicator


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Package Instructions for SAUE Testing Set 2

Toxicity

The toxicity of the product is based on the toxicity of Fipronil. The toxic or harmful amount of Fipronil for an 11.4 kg child is 2.5mg/kg times 11.4kg, which equals **28.5mg**. Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1037mg/ml x 0.097 Fipronil] = **0.28ml for EPA REG No. 88966-E and 88966-R.**

A child failure is access to one blister of any size equal to or greater than 0.28ml for EPA REG No. 88966-E and 88966-R.

Failure

For the purposes of CRP testing EPA REG No. 88966-E and 88966-R **a child failure is access to one blister** for all sizes. Access to one blister is more than a toxic or harmful amount of Fipronil (28.5mg) for all sizes.

Child Failure is defined as access to one blister, any breach, rip, tear, hole, or penetration of the blister, any visible incision or opening of the blister, any leakage of placebo from blister during or after test, or any partial or complete access to the placebo (water).

Senior Failure is failure to access the blister in the prescribed test time of 5 minutes for the first package or 1 minute for the second package, or inability to remove the pipette in the blister in condition suitable for intended use or removal of the pipette in the blister resulting in significant exposure to pipette contents.

Analysis of Data and Conclusion

The CRP certifications were dated February 28, 2012. These February 28, 2012 CRP certifications for EPA REG No. 88966-E and 88966-R are acceptable. The labels for EPA REG No. **88966-E** (0.67ml, 1.34ml, 2.68ml, 4.02ml) and **88966-R** (0.5ml) submitted February 28, 2012 use the same SAUE directions that are on the back of the blister and the Package Instructions for SAUE Testing **Set 2** that were given to the seniors during CRP testing (see packaging section for exact instructions).

Provided EPA REG No. **88966-E** and **88966-R** are being packaged into the CRP blister in strips of three blisters per card by Klocke Verpackungs-Service GMBH in Germany (confirmed by email Ann Tillman to Rosalind Gross May 14, 2012) the data matrix citations for MRID 48703501, 48703502, 48703503, 48703504, and 48652701 for EPA REG No. **88966-E** and MRID 48755301 and 48703504 for EPA REG No. **88966-R** may be used to demonstrate the CRE requirements in 16 CFR 1700.20 and SAUE effectiveness specifications in 16 CFR 1700.15(b)(2)(i) when tested in accordance with 16 CFR 1700.20. MRID 48703501, 48703502, 48703503, 48703504, and 48652701 for EPA REG No. **88966-E** and MRID 48755301 and 48703504 for EPA REG No. **88966-R** indicate the 0.67ml, 1.34ml, 2.68ml, 4.02ml, and 0.5ml sizes meet

the CRE requirements in 16 CFR 1700.20 and SAUE effectiveness specifications in 16 CFR 1700.15(b)(2)(i) when tested in accordance with 16 CFR 1700.20.

The study for 0.5ml KVS 201106 - Child 10-028 Senior 11-043 MRID 48755301 has been submitted twice. For the results for the 0.5ml size see KVS 201106 see MRID 48771101 in review by Rosalind L. Gross April 27, 2012 [DP397839, 400331, 397834, 400678; EPA REG No. 88051-E and 88051-R]. For the results for the 0.67, 1.34, and 4.02 sizes see MRID 48703501, 48703502, 48703503, and 48703504 in review by Rosalind L. Gross April 27, 2012 [DP397839, 400331, 397834, 400678; EPA REG No. 88051-E and 88051-R]. The results for 2.68ml size see MRID 48652701 in review by Rosalind L. Gross April 19, 2012 [DP398108, 399748, 398115, 399746, 398123, 399747, 398262, 399749, 399560, 399565; EPA Registration No. 88052-G, 88052-R, 88052-E, 88052-L, 88052-A, 88052-T]. **For the details of each study refer to the attached summary chart (selfcert&reviewsummary88966-1,2.doc).**

In conclusion all the requirements for CRP have been met for EPA Registration No. 88966-E and 88966-R. The directions on opening the package given to consumers must be identical to those given to the seniors during testing (see packaging section).

Should any human experience/epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.

Tru Prodigy

May 29, 2012

Tru Prodigy

CRP data review for EPA Reg No. 88966-E, 88966-R

Note: Tox/harm = 28.5mg Fipronil for EPA Reg No. 88966-E, 88966-R.

Child Fail = is access to one blister of any size equal to or greater than 0.28ml for EPA Reg No. 88966-E, 88966-R.

Child Failure is defined as access to one blister, any breach, rip, tear, hole, or penetration of the blister, any visible incision or opening of the blister, any leakage of placebo from blister during or after test, or any partial or complete access to the placebo (water).

Senior Failure is failure to access the blister in the prescribed test time of 5 minutes for the first package or 1 minute for the second package, or inability to remove the pipette in blister in condition suitable for intended use or removal of the pipette in blister resulting in significant exposure to pipette contents.

Pipette is in blister. Pipette has clear plastic front and foil backing.

Blister is CRP feature. Blister backing is PET/AL/PET/PE 12/12/12/75, which appears as a foil color. Blister front is PET/PP/PE transp. LDPE 350/100/75, which appears as a clear color.

SAUE directions on the back of the blister are a pictorial showing the separation of one of the three attached blisters and removing the pipette from the blister that repeats for the height of the blister and a dashed line with a picture of a scissors to the right of the pictorial showing where to separate one of the three attached blisters.

There are also SAUE directions in a leaflet that were given to the test subjects. This set of instructions is referred to in this review as Package Instructions for SAUE Testing Set 2. See attached page for these instructions.

The study for 0.5ml KVS 201106 - Child 10-028 Senior 11-043 MRID 48755301 has been submitted twice. For the results for the 0.5ml size see KVS 201106 see MRID 48771101 in review by Rosalind L. Gross April 27, 2012 [DP397839, 400331, 397834, 400678; EPA REG No. 88051-E and 88051-R].

For the results for the 0.67, 1.34, and 4.02 sizes see MRID 48703501, 48703502, 48703503, and 48703504 in review by Rosalind L. Gross April 27, 2012 [DP397839, 400331, 397834, 400678; EPA REG No. 88051-E and 88051-R].

The results for 2.68ml size KVS201104 in this table are from MRID 48652701. For additional information see per the data matrix MRID 48652701 in review by Rosalind L. Gross April 19, 2012 [DP398108, 399748, 398115, 399746, 398123, 399747, 398262, 399749, 399560, 399565; EPA Registration No. 88052-G, 88052-R, 88052-E, 88052-L, 88052-A, 88052-T]

EPA Reg #	mrid NCRT number	Fl. Oz.(29.6 ml =1 fl.oz)	ml (ml = 0.033 8fl. oz.)	# Pkges Child Get at Begin Test	CRE num child fail & # child test	SAUE	Conclusion
88966-E Dog	48703501 Child 10-030 Senior 11-044 KVS 201107	0.023	0.67	1 card with 3 blisters attached to each other	2 child failures of 50 child test Each access 1 unit 1 failure 1 st 5 min 1 failure 2 nd 5 min	94% 4 failures pkg A. 2 failures pkg B	Meet 16 CFR 1700.20 CRE Criteria - Yes pass 50 child test Meet 16 CFR 1700.20 SAUE Criteria - Yes CRP Cert dated 2/28/12 acceptable Pkg Instruct for SAUE Set 2 see attached page label submit 2/28/12 meets package instructions for SAUE testing set 2 and has SAUE testing instructions on back of blister all requirements for CRP per 16 CFR 1700.20 - Yes
88966-E Dog	48703502 Child 10-032 Senior 11-045 KVS 201108	0.045	1.34	1 card with 3 blisters attached to each other	2 child failures of 50 child test Each access 1 unit 2 failures 2 nd 5min	94% 4 failures pkg A. 2 failures pkg B	Meet 16 CFR 1700.20 CRE Criteria - Yes pass 50 child test Meet 16 CFR 1700.20 SAUE Criteria - Yes CRP Cert dated 2/28/12 acceptable Pkg Instruct for SAUE Set 2 see attached page label submit 2/28/12 meets package instructions for SAUE testing set 2 and has SAUE testing instructions on back of blister all requirements for CRP per 16 CFR 1700.20 - Yes

Tru Prodigy

EPA Reg #	mrid NCRT number	Fl. Oz.(29.6 ml =1 fl.oz)	ml (ml = 0.033 8fl. oz.)	# Pkges Child Get at Begin Test	CRE num child fail & # child test	SAUE	Conclusion
88966-E Dog	48652701 Child 10-034 Senior 11-046 KVS 201104 by cited data & in summary 48703504 KVS 201110	0.091	2.68	1 card with 3 blisters attached to each other	2 child failures of 50 child test Each access 1 unit 1 failure 1 st 5 min and 1 failure 2 nd 5 min.	95% 1 failure pkg A 4 failures pkg B	Meet 16 CFR 1700.20 CRE Criteria - Yes pass 50 child test Meet 16 CFR 1700.20 SAUE Criteria - Yes CRP Cert dated 2/28/12 acceptable Pkg Instruct for SAUE Set 2 see attached page label submit 2/28/12 meets package instructions for SAUE testing set 2 and has SAUE testing instructions on back of blister all requirements for CRP per 16 CFR 1700.20 - Yes
88966-E Dog	48703503 Child 10-036 Senior 11-047 KVS 201109	0.136	4.02	1 card with 3 blisters attached to each other	2 child failures of 50 child test Each access 1 unit 2 failures 2 nd 5 min.	93% 1 failure pkg A. 6 failures pkg B.	SAS & Comprehensive this size Meet 16 CFR 1700.20 CRE Criteria - Yes pass 50 child test Meet 16 CFR 1700.20 SAUE Criteria - Yes CRP Cert dated 2/28/12 acceptable Pkg Instruct for SAUE Set 2 see attached page label submit 2/28/12 meets package instructions for SAUE testing set 2 and has SAUE testing instructions on back of blister all requirements for CRP per 16 CFR 1700.20 - Yes

Tru Prodigy

EPA Reg #	mrid NCRT number	Fl. Oz.(29.6 ml =1 fl.oz)	ml (ml = 0.033 8fl. oz.)	# Pkges Child Get at Begin Test	CRE num child fail & # child test	SAUE	Conclusion
88966-R Cat	48755301 identical to 48771101 Child 10-028 Senior 11-043 KVS 201106 & in summary 48703504 KVS 201110	0.017	0.5	1 card with 3 blisters attached to each other	2 child failures of 50 child test Each access 2 units 2 failures 2 nd 5 min	96% 3 failures pkg A. 1 failure pkg B	Meet 16 CFR 1700.20 CRE Criteria - Yes pass 50 child test Meet 16 CFR 1700.20 SAUE Criteria - Yes CRP Cert dated 2/28/12 acceptable Pkg Instruct for SAUE Set 2 see attached page label submit 2/28/12 meets package instructions for SAUE testing set 2 and has SAUE testing instructions on back of blister all requirements for CRP per 16 CFR 1700.20 - Yes

Tru Prodigy

Opening Instructions from Package Leaflet



Package Instructions for SAUE Testing Set 2

Child Resistant Packaging Certification
For Tru Prodigy's VetGuard for Cats
(EPA Registration No. 88966-)

OK Cat RLG
5-21-12

Registrant: Tru Prodigy
9417 Brodie Lane
Austin, TX 78748

I certify that the packaging that will be used for this product meets the standards of 40 CFR 157.32.

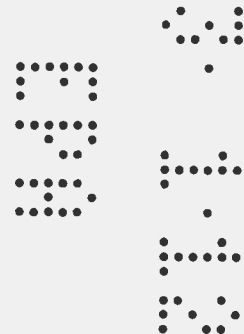
EPA Registration No. 88966-^R, VetGuard for Cats is **filled and packaged by Firma Klocke Verpackungs-Service GmbH**. The package consists of a placebo filled pipette with a clear plastic front and foil backing that is contained in a blister. The blister has a clear plastic front (PET/PP/PE transp. LDPE – 350/100/75) and a foil backing (PET/AL/PET/PE – 12/12/12/75). Three blisters are connected to each other. The blister is the child-resistant packaging. The pipette has one fill level, which is 0.017 fl. oz. (0.5 mL). Child Resistant Packaging, CRP, testing was conducted on the blister with a placebo filled pipette at 0.5mL (MRID, pending – NCRT Child study no. 10-028 and NCRT Senior 11-043).

I realize that additional CRP testing may be required if EPA Registration No. 88966- , VetGuard for Cats is **not filled and packaged by Firma Klocke Verpackungs-Service GmbH on the same equipment as the samples tested** (0.5mL (MRID pending – NCRT Child study no. 10-028 and NCRT Senior 11-043)). Further, any change in CRP opening instructions from those used in testing, color, size, and/or materials for the CRP may result in additional CRP testing for EPA Registration No. 88966- , VetGuard for Cats.



Ann M. Tillman
Agent for Tru Prodigy
Pyxis Regulatory Consulting, Inc.

Feb. 28, 2012
Date



21-Day Screen Completed by
Contractor

21-Day Expires on 3-22-12

Jacket # 88966-R

MRID# 487553

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

Stephen Schable

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 3-1-12

Experts In-Processing Signature: MF HARRINGTON Date 3-5-12 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date

EPA Reg. Number: <u>88966-R</u>		EPA Receipt Date: <u>3-1-12</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A) <u>NO N-Food</u>	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

Initially there were inert trade names not on OIPIN. The relevant MSDS's from the studies had enough information to determine that they were approved for non-food use. This was passed to the inerts team with a request to add them to OIPIN.

Joan passed.

Inerts Approved for Non-Food Use

RN
3/13/12

Studies passed 11-3 review.

MK1D487553

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/opbpbpd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 2, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-461924
EPA File Symbol or Registration Number: 88966-R
Product Name: VETGUARD FOR CATS
EPA Receipt Date: 01-Mar-2012
EPA Company Number: 88966
Company Name: TRU PRODIGY ANIMAL HEALTH, LLC

ANN TILLMAN
PYXIS REGULATORY CONSULTING, LLC
TRU PRODIGY ANIMAL HEALTH, LLC
4110 136TH ST. NW
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310.1
NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);Reduced Fee:
Linked to PRIA Application;

The fee for this action is \$1,434. You have paid \$4,807 towards this action. A refund in the amount of \$3,373 will be sent to you when this action is completed.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "m/lla".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

M
{912562#~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 10

Receipt No.

S-

912562

EPA File Symbol/Reg. No.

88966-R

Pin-Punch Date:

3/1/2012

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R310.1

Granted:

R310.1

Amount Due: \$ 4807⁰⁰

Parent/Child Decisions:

88966-E / 88966-R

NON-FOOD
☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: *[Signature]*

Date: *3/2/12*

Remarks:

Receipt for Section 3

S: 912562

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 88966 TRU PRODIGY ANIMAL HEALTH, LLC

V

Risk Manager: Registration Division, Risk Management Team 10

Product #: 88966-R Product Name: VETGUARD FOR CATS

Override#:

Me Too Section3: 85331-2 Me Too Product Name: FRONTLINE TOP SPOT FOR CATS

Application Date: 28-Feb-2012

OPP Rec'vd Date: 01-Mar-2012

Front End Date: 01-Mar-2012

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description: New registration

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

New Ingredient Request Date:

New Ingredient Received Date:

View/Edit

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF

282

Emma Becker

From: paygovadmin@mail.doc.twai.gov
Sent: Tuesday, February 28, 2012 11:02 AM
To: Emma Becker
Subject: Pay.Gov Payment Confirmation

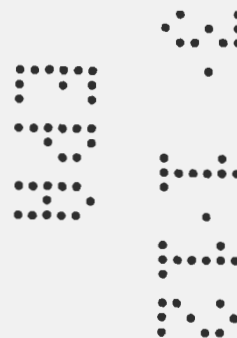
THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

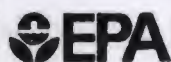
Transaction Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 255TDJM5
Agency Tracking ID: 74286812871
Transaction Type: Sale
Transaction Date: Feb 28, 2012 2:01:53 PM

Account Holder Name: Ann Tillman
Transaction Amount: \$4,807.00
Billing Address: 4110 136th St. NW
City: Gig Harbor
State/Province: WA
Zip/Postal Code: 98332
Country: USA
Card Type: AmericanExpress
Card Number: *****1031

Decision Number:
Registration Number:
Company Name: Tru Prodigy
Company Number: ~~67505~~ 88966
Action Code: R310.1





United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Tru Prodigy/88966- <i>R</i>	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Tru Prodigy/VetGuard for Cats	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Tru Prodigy c/o Pyxis Regulatory Consulting 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 65331-2 Product Name Frontline Top Spot for Cats	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application falls under under Category R310.1 (48: New end use product; requires review of data package within RD). The fee due which has been paid is \$4,807 with a PRIA decision time line of 6 months. This application is a secondary application and is linked to a primary application (VetGuard for Dogs).

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. 0.017 oz. No. per container 3	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 0.051 fl. oz.	5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other on box and on insert in box	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name An M. Tillman	Title Agent	Telephone No. (Include Area Code) (253) 853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Ann M. Tillman</i>	3. Title Agent	
4. Typed Name Ann M. Tillman	5. Date 2/28/12	

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

February 28, 2012

OVERNIGHT DELIVERY

Richard Gebken (PM 10)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Tru Prodigy
VetGuard for Cats (EPA File Symbol 88966-^R)
Application for New Pesticide Registration
PRIA Category R310.1 (Secondary Application)

Dear Mr. Gebken,

On behalf of Tru Prodigy, we are submitting an application for registration of VetGuard for Cats, an end use product that contains the active ingredient fipronil. This application is tied to the primary application for VetGuard for Dogs. VetGuard for Cats is the identical formulation as VetGuard for Dogs.

In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4) Basic and Alternate #1
3. Three (3) Copies of the Proposed Labeling
4. A CD containing an electronic version of the label
5. Certification with Respect to Label Integrity
6. Agency Internal Use Copy of the Data Matrix
7. Public File Copy of the Data Matrix
8. Certification with Respect to Citation of Data (EPA Form 8570-34)
9. Formulator's Exemption Statement (EPA Form 8570-27)
10. Child Resistant Packaging Certification
11. Copy of the PRIA payment from pay.gov
12. Copy of the cover letter for VetGuard for Dogs, the primary application
13. Letter of authorization from sponsor of CRP testing
14. Letter of Authorization
15. Product Specific Data (3 copies each):

Volume 1	US 16 CFR § 1700	Novosad, M. Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 0.5 mL Capacity. Report Number KVS-201106. December 9, 2011 (Child 10-028; Adult 11-043).
----------	------------------	---

Tru Prodigy believes this application falls under Category R310.1 (48: New product; requires review of data within RD) because it is a secondary application linked to the submission of the application for registration of VetGuard for Dogs and requires review of data within RD. The fee due which has been paid is \$4,807 with a PRIA decision time line of 6 months. Tru Prodigy's VetGuard for Cats qualifies for the Formulator's Exemption for fipronil generic data requirements.

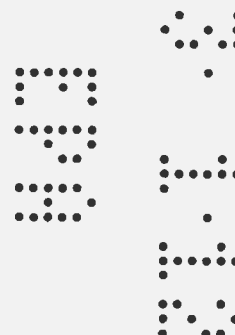
We trust you will find this application complete. However, please feel free to contact me by email at Ann@PyxisRC.com or by phone ((253) 853-7369) if you have any questions or need any additional information.

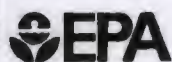
Sincerely,



Ann M. Tillman

Enclosures





United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Tru Prodigy/88966-	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Tru Prodigy/VetGuard for Cats	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Tru Prodigy c/o Pyxis Regulatory Consulting 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 65331-2 Product Name Frontline Top Spot for Cats	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application falls under under Category R310.1 (48: New end use product; requires review of data package within RD). The fee due which has been paid is \$4,807 with a PRIA decision time line of 6 months. This application is a secondary application and is linked to a primary application (VetGuard for Dogs).

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.017 oz.	No. per container 3	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 0.051 fl. oz.		5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other on box and on insert in box			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)				
Name Ann M. Tillman		Title Agent		Telephone No. (Include Area Code) (253) 853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.				Date Application Received (Stamped)
2. Signature 		3. Title Agent		
4. Typed Name Ann M. Tillman		5. Date 2/28/12		

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

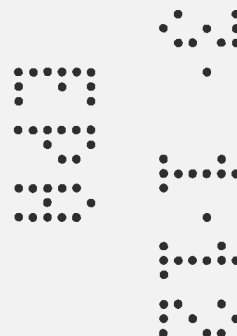
PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
088966-xxxxx	Feb. 28, 2012	088966-xxxxx.20120228.VetGuard for Cats Label.v1.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.



Signature
Ann M. Tillman
Agent for Tru Prodigy

Feb. 28, 2012
Date



There is an **ELECTRONIC LABEL** for this action

You can use Acrobat to compare the e-label to the previous version (and find the changes). You can also use Acrobat to mark-up the e-label with your comments.

If e-label was submitted via

CD-ROM with paper application

then you will find e-label in

Electronic Label Library

If the e-label is not found in the ELL then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the Front End.

or

If e-label was submitted via

XML E-Submission (no paper)

then you will find e-label in

Documentum

See overview of processing e-labels on other side of this sheet.

If you have any questions on e-labels, please contact one of your division e-label experts:

AD	Willie Abney	308-1689
	Rena Whitaker	308-7003
	Tracy Lantz	308-6415
BPPD		
RD	Tom Harris	308-9423



500 E. Shore Dr. Suite 120 Eagle, Idaho 83616 Ph: (208) 939-8900 Fax: 208-939-3200

January 3, 2012

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Ann Tillman, Mike Kellogg, Leanne Pruett, Ross Gilbert, Janelle Kay, Maryanne Geisbush or Arianna Shorey of Pyxis Regulatory Consulting, Inc. is authorized to act as agent for Tru Prodigy, LLC (EPA Company Number [pending]), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

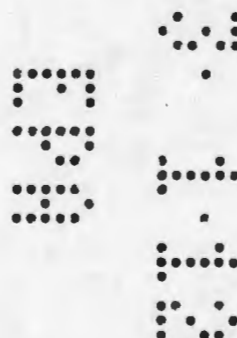
If you have any questions, please do not hesitate to contact me at 208-939-8900 x311.

Sincerely,

Cord Christensen

CEO

cc: Pyxis Regulatory Consulting, Inc.





United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748	EPA File Symbol/Registration Number 88966-
	Product Name VetGuard for Cats
	Date of Confidential Statement of Formula (EPA Form 8570-4) 02/24/2012

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

fipronil

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Fipronil	[REDACTED]	[REDACTED]
Signature 	Name and Title Ann M. Tillman, Agent	Date 2/28/12

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment

R 310

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI). Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or (NO) (circle one)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGAI	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	✓					
830.1600	Description of materials used to produce the product	✓					
830.1650	Description of formulation process	✓					
830.1670	Discussion on the formation of impurities	✓					
830.1700	Preliminary analysis		✓				
830.1750	Certified limits (158.345)	✓					
830.1800	Enforcement analytical method	✓					

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGAI	
		Yes	No	Yes	No	Yes	No
830.6302	Color	✓					
830.6303	Physical State	✓					
830.6304	Odor	✓					
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical incompatibility)	✓					
830.6315	Flammability	✓					
830.6316	Explosibility		✓				
830.6317	Storage stability		✓				
830.6319	Miscibility		✓				
830.6320	Corrosion Characteristics		✓				
830.6321	Dielectric Breakdown Voltage		✓				
830.7000	pH	✓					
830.7050	UV/ Visible Absorption						
830.7100	Viscosity	✓					
830.7200	Melting Point						
830.7220	Boiling Point						
830.7300	Density	✓					
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

Grayed out = data not required

R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited	
		Yes	No	Yes	No
870.1100	Acute Oral (LD50)				
870.1200	Acute Dermal (LD50)				
870.1300	Acute Inhalation (LC50)				
870.2400	Acute Eye Irritation				
870.2500	Acute Dermal Irritation				
870.2600	Dermal Sensitization				

Efficacy – which guideline is used depends on the proposed label use

Guideline No.	Study Title	Data submitted		Cited		Comments
		Yes	No	Yes	No	
810.3100	Soil Treatments for Imported Fire Ants					NA
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments					
810.3300	Treatments to Control Pests of Humans and Pets			X		CITE ALL
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					N/A
810.3500	Premises Treatments					
810.3600	Structural Treatments					
810.3800	Methods for Efficacy Testing of Termite Baits					



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Tru Prodigy c/o Pyxis Regulatory Consulting, 4110 136th St NW, Gig Harbor WA 98332 (253)853-7369	EPA Registration Number/File Symbol 88966-
Active Ingredient(s) and/or representative test compound(s) Fipronil	Date 2/28/12
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Residential Indoor	Product Name VetGuard for Cats

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Ann M. Tillman</i>	Date 2/28/12	Typed or Printed Name and Title Ann M. Tillman, Agent
------------------------------------	-----------------	--

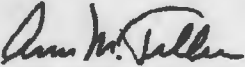
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DATA MATRIX

Date Mar. 30, 2012		EPA Reg. No./File Symbol 88966- <i>R</i>		Page / of 7	
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748		Product VetGuard for Cats			
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	Volume 1 of primary application	Tru Prodigy	OWN	See endnote 1 for primary application ¹
830.1600	Description of Materials Used to Produce the Product	Volume 1 of primary application	Tru Prodigy	OWN	See Endnote 1
830.1620	Description of Production Process				Not required ²
830.1650	Description of Formulation Process	Volume 1 of primary application	Tru Prodigy	OWN	See Endnote 1
830.1670	Discussion of Formation of Impurities	Volume 1 of primary application	Tru Prodigy	OWN	See Endnote 1
830.1700	Preliminary Analysis				Not Required ³
830.1750	Certified Limits	Volume 1 of primary application	Tru Prodigy	OWN	See Endnote 1
830.1800	Enforcement Analytical Method	Volume 1 of primary application	Tru Prodigy	OWN	See Endnote 1
830.6302	Color	Volume 2 of primary application	Tru Prodigy	OWN	See Endnote 1
830.6303	Physical State	Volume 2 of primary application	Tru Prodigy	OWN	See Endnote 1
Signature 			Name and Title Ann M. Tillman, Consultant		Date Mar. 30, 2012


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DATA MATRIX


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Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748			Product VetGuard for Cats		
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6304	Odor	Volume 2 of primary application	Tru Prodigy	OWN	See Endnote 1
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions				Not Required ⁴
830.6314	Oxidation/Reduction: Chemical Incompatibility	Volume 2 of primary application	Tru Prodigy	OWN	See Endnote 1
830.6315	Flammability	Volume 2 of primary application	Tru Prodigy	OWN	See Endnote 1
830.6316	Explodability	Volume 3 of primary application	Tru Prodigy	OWN	Waiver ⁵
830.6317	Storage Stability	Volume 3 of primary application	Tru Prodigy	OWN	PRN 92-5 ⁶
830.6319	Miscibility				Not required ⁷
830.6320	Corrosion Characteristics	Volume 3 of primary application	Tru Prodigy	OWN	PRN 92-5 ⁶
830.6321	Dielectric Breakdown Voltage				Not required ⁸
830.7000	pH	Volume 2 of primary application	Tru Prodigy	OWN	See Endnote 1
830.7050	UV/Visible Absorption				
830.7100	Viscosity	Volume 2 of primary application	Tru Prodigy	OWN	See Endnote 1
Signature 			Name and Title Ann M. Tillman, Consultant		Date Mar. 30, 2012

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Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748		Product VetGuard for Cats			
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7200	Melting Point/Melting Range				Not required ⁹
830.7220	Boiling Point/Boiling Range				Not required ⁸
830.7300	Density/Relative Density/Bulk Density	Volume 2 of primary application	Tru Prodigy	OWN	See Endnote 1
830.7370	Dissociation Constants in Water				Not required ⁸
830.7520	Particle size, fiber length, diameter distribution	Volume 3 of primary application	Tru Prodigy	OWN	Waiver ¹⁰
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Not required ⁸
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550
830.7840	Water Solubility: Column Elution Method; Shake Flask Method				Not required ⁸
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure				Not required ⁸
Signature 			Name and Title Ann M. Tillman, Consultant		Date Mar. 30, 2012


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Date Mar. 30, 2012			EPA Reg. No./File Symbol 88966-		Page 4 of 7
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748			Product VetGuard for Cats		
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute Oral Toxicity: Rat	Cite-all 43577705 43951703		PAY OLD OLD	
870.1200	Acute Dermal Toxicity: Rat	Cite-all 43577706		PAY OLD	
870.1300	Acute Inhalation Toxicity: Rat	Cite-all 43577707		PAY OLD	
870.2400	Primary Eye Irritation: Rabbit	Cite-all 43577708		PAY OLD	
870.2500	Primary Dermal Irritation	Cite-all 43577709		PAY OLD	
870.2600	Dermal Sensitization	Cite-all 43577710		PAY OLD	
870.7200	Companion Animal Safety	Cite-all		PAY	
810.3300	Product Performance	Cite-all		PAY	
US 16 CFR § 1700	Child Resistant Packaging Study	Volume 1 of this submission 48703054 504	Tru Prodigy Chanelle Pharmaceuticals Manufacturing Ltd.	PER PER	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Mar. 30, 2012


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DATA MATRIX

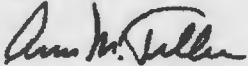
Date Mar. 30, 2012		EPA Reg. No./File Symbol 88966-		Page 5 of 7	
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748		Product VetGuard for Cats			
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Fipronil Generic Data Requirements					
VetGuard for Cats qualifies for Formulator's Exemption for fipronil generic data requirements.					
Fipronil Product Specific Data Requirements					
Tru Prodigy will make offers-to-pay to the following companies on the fipronil data submitters list of September 30, 2011.					
		Cite-All	Syngenta Crop Protection LLC	PAY	
		Cite-All	The Scotts Company	PAY	
		Cite-All	Bayer Cropscience LP	PAY	
		Cite-All	Bayer Environmental Science	PAY	
		Cite-All	Whitmire Micro-Gen Research Laboratories	PAY	
		Cite-All	Virbac AH, Inc.	PAY	
		Cite-All	Sergeant's Pet Care Products, Inc.	PAY	
		Cite-All	The Hartz Mountain Corp.	PAY	
		Cite-All	Reckitt Benckiser LLC	PAY	
		Cite-All	Cheminova A/S	PAY	
		Cite-All	J. J. Mauget Co.	PAY	
Signature 		Name and Title Ann M. Tillman, Consultant		Date Mar. 30, 2012	

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Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748		Product VetGuard for Cats			
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	BASF Corp.	PAY	
		Cite-All	Chemsico	PAY	
		Cite-All	Makhteshim Chemical Works Ltd.	PAY	
		Cite-All	Control Solutions Inc.	PAY	
		Cite-All	Virbac	PAY	
		Cite-All	Combat Insect Control Systems	PAY	
		Cite-All	Merial Limited	PAY	
		Cite-All	Spray Drift Task Force	PAY	
		Cite-All	Cheminova Inc.	PAY	
		Cite-All	Outdoor Residential Exposure Task Force	PAY	
		Cite-All	Agricultural Reentry Task Force	PAY	
		Cite-All	Ambrands	PAY	
		Cite-All	Innovative Pest Control Products	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Mar. 30, 2012

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Date Mar. 30, 2012			EPA Reg. No./File Symbol 88966-		Page 7 of 7
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748			Product VetGuard for Cats		
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	FIFRA Endangered Species Task Force	PAY	
		Cite-All	Irvita Plant Protection N.V.	PAY	
		Cite-All	Residential Exposure Joint Venture	PAY	
		Cite-All	Agricultural Handlers Exposure Task Force	PAY	
		Cite-All	Norbrook, Inc.	PAY	
		Cite-All	Loradochem, Inc.	PAY	
		Cite-All	Zhejiang Hisun Pharmaceuticals Co., Ltd.	PAY	
		Cite-All	Argite - Fipronil LLC	PAY	
		Cite-All	Firponex Solutions Inc.	PAY	
		Cite-All	Virbac S. A.	PAY	
		Cite-All	Raymat Materials Inc.	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Mar. 30, 2012

Endnotes for Data Matrix for VetGuard for Cats

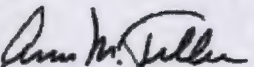
-
- ¹ Where noted, data have been submitted with the primary application for registration for VetGuard for Dogs. VetGuard for Cats is the exactly the same formulation as VetGuard for Dogs.
- ² **830.1620** – These data are not required for the registration of an end-use product. See 830.1650 for formulation process information.
- ³ **830.1700** – This product does not consist solely of the technical grade active ingredient (TGA) and is not produced by an integrated system, therefore, per OPPTS 830.1700, these data are not required.
- ⁴ **830.6313** – These data are not required for registration of an end-use product.
- ⁵ **830.6316** - Tru Prodigy requests a waiver from this data requirement because fipronil does not have the chemical bonds or functional groups associated with explosive chemicals. There are no potentially explosive ingredients in VetGuard for Cats (refer to the CSF for VetGuard for Cats).
- ⁶ **830.6317, 830.6320** - Per PR Notice 92-5, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Tru Prodigy agrees to conduct these studies if required as a condition of registration.
- ⁷ **830.6319** - This data requirement is required when the product is an emulsifiable liquid and to be diluted with petroleum solvents. VetGuard for Cats is not an emulsifiable concentrate and its labeling does not allow it to be diluted with petroleum solvents; therefore this data requirement is not applicable to VetGuard.
- ⁸ **830.6321** - These data are required if the product is an end-use product and is applied around electrical equipment. VetGuard is not to be applied around electrical equipment; therefore this data requirement is not applicable.
- ⁹ **830.7200, 830.7220, 830.7370, 830.7550-7570, 830.7840-7860, 830.7950** – These data are not required for registration of an end-use product.
- ¹⁰ **830.7520** – Tru Prodigy requests a waiver for this data requirement for VetGuard because the product is not a fibrous material and is not a water-insoluble material

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DATA MATRIX


Date Mar. 30, 2012			EPA Reg. No./File Symbol 88966-		Page 4 of 7
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748			Product VetGuard for Cats		
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute Oral Toxicity: Rat	Cite-all 43577705 43951703		PAY OLD OLD	
870.1200	Acute Dermal Toxicity: Rat	Cite-all 43577706		PAY OLD	
870.1300	Acute Inhalation Toxicity: Rat	Cite-all 43577707		PAY OLD	
870.2400	Primary Eye Irritation: Rabbit	Cite-all 43577708		PAY OLD	
870.2500	Primary Dermal Irritation	Cite-all 43577709		PAY OLD	
870.2600	Dermal Sensitization	Cite-all 43577710		PAY OLD	
870.7200	Companion Animal Safety	Cite-all	65331-2	PAY	
810.3300	Product Performance	Cite-all		PAY	
US 16 CFR § 1700	Child Resistant Packaging Study	Volume 1 of this submission 48703054	Tru Prodigy Chanelle Pharmaceuticals Manufacturing Ltd.	PER PER	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Mar. 30, 2012

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DATA MATRIX

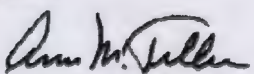
Date Mar. 30, 2012			EPA Reg. No./File Symbol 88966-		Page 3 of 7
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748			Product VetGuard for Cats		
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7200	Melting Point/Melting Range				Not required ⁹
830.7220	Boiling Point/Boiling Range				Not required ⁸
830.7300	Density/Relative Density/Bulk Density	Volume 2 of primary application	Tru Prodigy	OWN	See Endnote 1
830.7370	Dissociation Constants in Water				Not required ⁸
830.7520	Particle size, fiber length, diameter distribution	Volume 3 of primary application	Tru Prodigy	OWN	Waiver ¹⁰
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Not required ⁸
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550
830.7840	Water Solubility: Column Elution Method; Shake Flask Method				Not required ⁸
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure				Not required ⁸
Signature 			Name and Title Ann M. Tillman, Consultant		Date Mar. 30, 2012

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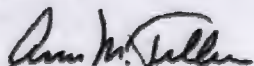
Date Mar. 30, 2012			EPA Reg. No./File Symbol 88966-		Page 2 of 7
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748			Product VetGuard for Cats		
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6304	Odor	Volume 2 of primary application	Tru Prodigy	OWN	See Endnote 1
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions				Not Required ⁴
830.6314	Oxidation/Reduction: Chemical Incompatibility	Volume 2 of primary application	Tru Prodigy	OWN	See Endnote 1
830.6315	Flammability	Volume 2 of primary application	Tru Prodigy	OWN	See Endnote 1
830.6316	Explodability	Volume 3 of primary application	Tru Prodigy	OWN	Waiver ⁵
830.6317	Storage Stability	Volume 3 of primary application	Tru Prodigy	OWN	PRN 92-5 ⁶
830.6319	Miscibility				Not required ⁷
830.6320	Corrosion Characteristics	Volume 3 of primary application	Tru Prodigy	OWN	PRN 92-5 ⁶
830.6321	Dielectric Breakdown Voltage				Not required ⁸
830.7000	pH	Volume 2 of primary application	Tru Prodigy	OWN	See Endnote 1
830.7050	UV/Visible Absorption				
830.7100	Viscosity	Volume 2 of primary application	Tru Prodigy	OWN	See Endnote 1
Signature 			Name and Title Ann M. Tillman, Consultant		Date Mar. 30, 2012

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DATA MATRIX

Date Mar. 30, 2012			EPA Reg. No./File Symbol 88966- R		Page / of 7
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748			Product VetGuard for Cats		
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	Volume 1 of primary application	Tru Prodigy	OWN	See endnote 1 for primary application ¹
830.1600	Description of Materials Used to Produce the Product	Volume 1 of primary application	Tru Prodigy	OWN	See Endnote 1
830.1620	Description of Production Process				Not required ²
830.1650	Description of Formulation Process	Volume 1 of primary application	Tru Prodigy	OWN	See Endnote 1
830.1670	Discussion of Formation of Impurities	Volume 1 of primary application	Tru Prodigy	OWN	See Endnote 1
830.1700	Preliminary Analysis				Not Required ³
830.1750	Certified Limits	Volume 1 of primary application	Tru Prodigy	OWN	See Endnote 1
830.1800	Enforcement Analytical Method	Volume 1 of primary application	Tru Prodigy	OWN	See Endnote 1
830.6302	Color	Volume 2 of primary application	Tru Prodigy	OWN	See Endnote 1
830.6303	Physical State	Volume 2 of primary application	Tru Prodigy	OWN	See Endnote 1
Signature 			Name and Title Ann M. Tillman, Consultant		Date Mar. 30, 2012

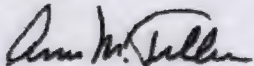
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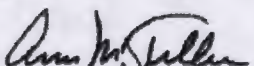
DATA MATRIX

Date Mar. 30, 2012		EPA Reg. No./File Symbol 88968-		Page 5 of 7	
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748		Product VetGuard for Cats			
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Fipronil Generic Data Requirements					
VetGuard for Cats qualifies for Formulator's Exemption for fipronil generic data requirements.					
Fipronil Product Specific Data Requirements					
Tru Prodigy will make offers-to-pay to the following companies on the fipronil data submitters list of September 30, 2011.					
		Cite-All	Syngenta Crop Protection LLC	PAY	
		Cite-All	The Scotts Company	PAY	
		Cite-All	Bayer Cropscience LP	PAY	
		Cite-All	Bayer Environmental Science	PAY	
		Cite-All	Whitmire Micro-Gen Research Laboratories	PAY	
		Cite-All	Virbac AH, Inc.	PAY	
		Cite-All	Sergeant's Pet Care Products, Inc.	PAY	
		Cite-All	The Hartz Mountain Corp.	PAY	
		Cite-All	Reckitt Benckiser LLC	PAY	
		Cite-All	Cheminova A/S	PAY	
		Cite-All	J. J. Mauget Co.	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Mar. 30, 2012

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DATA MATRIX

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Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748		Product VetGuard for Cats			
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	BASF Corp.	PAY	
		Cite-All	Chemsico	PAY	
		Cite-All	Makhteshim Chemical Works Ltd.	PAY	
		Cite-All	Control Solutions Inc.	PAY	
		Cite-All	Virbac	PAY	
		Cite-All	Combat Insect Control Systems	PAY	
		Cite-All	Merial Limited	PAY	
		Cite-All	Spray Drift Task Force	PAY	
		Cite-All	Cheminova Inc.	PAY	
		Cite-All	Outdoor Residential Exposure Task Force	PAY	
		Cite-All	Agricultural Reentry Task Force	PAY	
		Cite-All	Ambrands	PAY	
		Cite-All	Innovative Pest Control Products	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Mar. 30, 2012

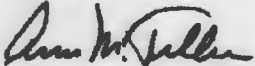
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DATA MATRIX

Date Mar. 30, 2012			EPA Reg. No./File Symbol 88986-		Page 7 of 7
Applicant's/Registrant's Name & Address Tru Prodigy 9417 Brodie Lane Austin, TX 78748			Product VetGuard for Cats		
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	FIFRA Endangered Species Task Force	PAY	
		Cite-All	Irvita Plant Protection N.V.	PAY	
		Cite-All	Residential Exposure Joint Venture	PAY	
		Cite-All	Agricultural Handlers Exposure Task Force	PAY	
		Cite-All	Norbrook, Inc.	PAY	
		Cite-All	Loradochem, Inc.	PAY	
		Cite-All	Zhejiang Hisun Pharmaceuticals Co., Ltd.	PAY	
		Cite-All	Argite - Fipronil LLC	PAY	
		Cite-All	Firponex Solutions Inc.	PAY	
		Cite-All	Virbac S. A.	PAY	
		Cite-All	Raymat Materials Inc.	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Mar. 30, 2012

Endnotes for Data Matrix for VetGuard for Cats

-
- ¹ Where noted, data have been submitted with the primary application for registration for VetGuard for Dogs. VetGuard for Cats is the exactly the same formulation as VetGuard for Dogs.
- ² **830.1620** – These data are not required for the registration of an end-use product. See 830.1650 for formulation process information.
- ³ **830.1700** – This product does not consist solely of the technical grade active ingredient (TGAI) and is not produced by an integrated system, therefore, per OPPTS 830.1700, these data are not required.
- ⁴ **830.6313** – These data are not required for registration of an end-use product.
- ⁵ **830.6316** - Tru Prodigy requests a waiver from this data requirement because fipronil does not have the chemical bonds or functional groups associated with explosive chemicals. There are no potentially explosive ingredients in VetGuard for Cats (refer to the CSF for VetGuard for Cats).
- ⁶ **830.6317, 830.6320** - Per PR Notice 92-5, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Tru Prodigy agrees to conduct these studies if required as a condition of registration.
- ⁷ **830.6319** - This data requirement is required when the product is an emulsifiable liquid and to be diluted with petroleum solvents. VetGuard for Cats is not an emulsifiable concentrate and its labeling does not allow it to be diluted with petroleum solvents; therefore this data requirement is not applicable to VetGuard.
- ⁸ **830.6321** - These data are required if the product is an end-use product and is applied around electrical equipment. VetGuard is not to be applied around electrical equipment; therefore this data requirement is not applicable.
- ⁹ **830.7200, 830.7220, 830.7370, 830.7550-7570, 830.7840-7860, 830.7950** – These data are not required for registration of an end-use product.
- ¹⁰ **830.7520** – Tru Prodigy requests a waiver for this data requirement for VetGuard because the product is not a fibrous material and is not a water-insoluble material

[Note to reviewer: optional text is placed in brackets]

[Package Insert, Text]

VETGUARD FOR CATS

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT:

Fipronil:.....9.7%

INERT INGREDIENTS:.....90.3%

TOTAL:.....100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[Optional marketing claims]

- ✓ [Quick-acting]
- ✓ [Long-lasting]
- ✓ [Does not wash off]
- ✓ [For monthly control of fleas, ticks, chewing lice, mosquitoes]
- ✓ [Kills fleas]
- ✓ [Kills newly emerged adult fleas prior to egg-laying]
- ✓ [Stops existing infestations. Prevents break-out of new infestations]
- ✓ [Effective treatment that kills fleas which may cause flea allergy dermatitis]
- ✓ [Kills all life stages of ticks (larva, nymph, and adult) including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]
- ✓ [Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases]
- ✓ [Kills Brown dog ticks, American dog ticks, Lone Star ticks and deer ticks for up to one month]
- ✓ [Eliminates chewing lice infestations]
- ✓ [Kills mosquitoes]

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

[Alternate text for bulk transport container label: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Only for repackaging into animal health products.]

[Alternate text for bulk transport container label: For Further Labeling and Repackaging Only. Not for Retail Sale or Use.]

[Package Insert, Text]

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS

CAUTION: Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

[Alternate text for bulk transport container label: **CAUTION:** Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

[Alternate text for bulk transport container label: **ENVIRONMENTAL HAZARDS**

This product is toxic to birds, fish, and aquatic invertebrates. Do not apply directly to water. Do not contaminate water by cleaning equipment or disposal of wastes. Do not contaminate water when disposing of equipment washwaters.]

HAZARD TO DOMESTIC ANIMALS

For external use only on cats. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. You may also contact SAFETYCALL INTERNATIONAL at 1-1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

Side Effects. After applying VetGuard for Cats, check your cat for side-effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea have been reported from grooming after treatment. If you observe these signs or symptoms in your treated cat, contact your veterinarian. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame.

VetGuard for Cats is approved for use on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks.

VetGuard for Cats keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

Frequency of Application

Monthly application of VetGuard for Cats ~~completely~~ controls flea, tick and chewing lice infestations. You can reapply VetGuard for Cats once every 30 days, if needed.

Fleas: VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply VetGuard for Cats every 30 days.

[Package Insert, Text]

Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open.

Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.

[ILLUSTRATIONS FOR APPLYING PRODUCT]

LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of Tru Prodigy. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Tru Prodigy makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither Tru Prodigy, the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

EPA Reg. No.: 88966-

EPA Est. No.:

Manufactured for:

Tru Prodigy
9417 Brodie Lane
Austin, TX 78748

[Made in Germany]

[VetGuard for Cats is a registered trade name of Tru Prodigy]

[Optional Bar Code]

[Optional text with Company logo]

[Carton Text - Back]

VETGUARD FOR CATS

VetGuard for Cats is approved for use on all cats including breeding, pregnant and lactating queens, and on kittens that are older than 8 weeks. VetGuard for Cats controls fleas, ticks, chewing lice and mosquitoes and keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain.

DIRECTIONS FOR USE

It is a violation of law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR CAT, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS OR ON OTHER ANIMALS.**

Side Effects. After applying VetGuard for Cats, check your cat for side-effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea have been reported from grooming after treatment. If you observe these signs or symptoms in your treated cat, contact your veterinarian. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588.

To kill fleas, ticks, chewing lice and mosquitoes apply VetGuard for Cats as follows:

Remove and Open Package

See package insert for opening instructions.

Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open.

Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry.

[ILLUSTRATIONS FOR APPLYING PRODUCT]

[Insert with Tips, Front Side, Text]

[Optional marketing claims]

[Picture of flea]

[Picture of tick]

[Picture of chewing lice]

[Picture of mosquitoes]

VetGuard for Cats

See other side for stickers to remind you it's time to reapply VetGuard for Cats.

Some Tips and Other Information for Using VetGuard for Cats

Treat dogs and cats separately and only with the proper dose of VetGuard for Dogs or VetGuard for Cats.

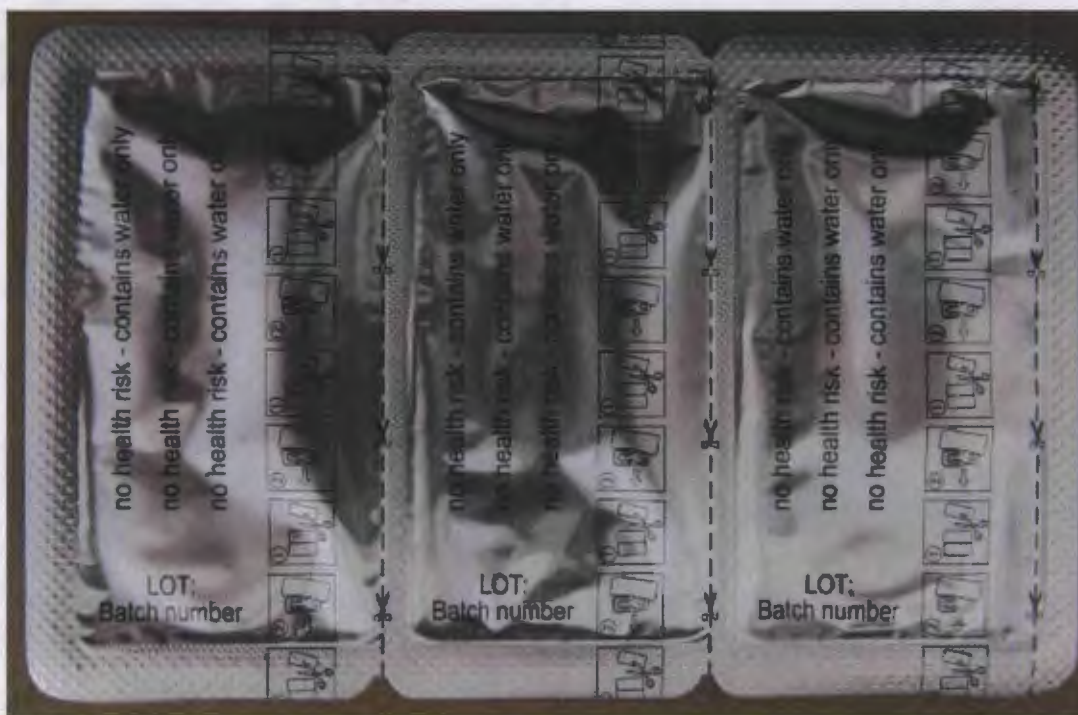
Follow the label instructions for how to apply and be sure that VetGuard for Cats is applied to the skin, not on top of the fur and not near the collar. Removing the collar before application may help to prevent the collar from absorbing the VetGuard dose.

Apply VetGuard for Cats when your cat is dry. Make sure you apply all of the dose that is in the applicator.

Even indoor cats need flea and tick control if other household pets bring fleas into the home.

Fleas have many life stages and serious infestations can take up to 3 applications every 30 days for ~~complete~~ control. In fact, the flea life-cycle in the home can last as long as 21 days.

[Pictogram of Back of Blister With Opening Instructions]



[Text for Back of Blister]

Keep Out of Reach of Children

CAUTION: See full label for additional instructions and precautions before using

Only for Cats & Kittens

VetGuard for Cats

EPA Reg. No. 88966-

Lot/Batch No.

0.017 fl. oz. (0.5 mL)

9.7% Fipronil